

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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IN RE BRISTOL-MYERS SQUIBB CO.	:	Case No. 1:21-cv-08255 (JMF)
CVR SECURITIES LITIGATION	:	
	:	ORAL ARGUMENT REQUESTED
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**MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS'  
MOTION TO DISMISS THE CONSOLIDATED COMPLAINT**

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Table of Contents

	<u>Page</u>
PRELIMINARY STATEMENT .....	1
BACKGROUND .....	4
A.    The Parties .....	4
B.    The Celgene Merger and the CVRs .....	5
C.    The FDA Applications .....	6
D.    Challenged Statements .....	9
E.    Plaintiffs' Claims .....	10
LEGAL STANDARDS .....	11
A.    Motions to Dismiss .....	11
B.    Elements of the Causes of Action .....	12
ARGUMENT .....	13
I.    PLAINTIFFS HAVE NOT PLAUSIBLY ALLEGED ANY SECURITIES CLAIM BASED ON THE JOINT PROXY STATEMENT / PROSPECTUS. ....	13
A.    The Complaint Does Not Allege a Material Misstatement or Omission in the Joint Proxy Statement / Prospectus. ....	13
1.    The PSLRA Safe Harbor Bars the Claims. ....	14
2.    Plaintiffs Do Not Otherwise Allege an Actionable Misstatement or Omission. ....	19
B.    Claims Based on the Proxy Statement "Sound in Fraud" But Are Not Pleaded With Particularity. ....	21
C.    Plaintiffs Have Not Plausibly Alleged Loss Causation for the § 14(a) Claims .....	22
II.   PLAINTIFFS HAVE NOT ALLEGED AN ACTIONABLE SECURITIES FRAUD CLAIM. ....	23
A.    Plaintiffs Have Not Alleged Any Actionable Misrepresentation. ....	23
1.    The Challenged Statements Were Accurate. ....	23

	<u>Page</u>
2. The Safe Harbor Bars Liability for Most of the Challenged Statements.....	27
3. Some Challenged Statements Were Inactionable Puffery or Opinions.....	28
B. Plaintiffs Have Not Alleged Facts That Give Rise to the Required “Strong Inference” of Scienter. ....	29
1. Plaintiffs’ Motive Allegations Are Implausible.....	29
2. The Complaint Does Not Plead Conscious Misbehavior or Recklessness. ....	32
C. Plaintiffs Have Not Plausibly Alleged Loss Causation. ....	34
III. THE “CONTROLLING PERSON” CLAIMS ALSO SHOULD BE DISMISSED. ....	35
CONCLUSION.....	35

Table of Authorities

	<u>Page(s)</u>
<u>Cases</u>	
<i>100 Orchard St., LLC v. Travelers Indem. Ins. Co. of Am.</i> , 2021 WL 2333244 (S.D.N.Y. June 8, 2021) .....	8
<i>Abramson v. Newlink Genetics Corp.</i> , 965 F.3d 165 (2d Cir. 2020).....	29
<i>Acito v. IMCERA Grp., Inc.</i> , 47 F.3d 47 (2d Cir. 1995).....	26
<i>In re Aegon N.V. Sec. Litig.</i> , 2004 WL 1415973 (S.D.N.Y. June 23, 2004) .....	14
<i>Amorosa v. Ernst &amp; Young</i> , 672 F. Supp. 2d 493 (S.D.N.Y. 2009).....	22
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	11
<i>In re AT&amp;T/DirecTV Now Sec. Litig.</i> , 480 F. Supp. 3d 507 (S.D.N.Y. 2020).....	30
<i>ATSI Commc'ns Inc. v. Shaar Fund, Ltd.</i> , 493 F.3d 87 (2d Cir. 2007).....	4, 13, 35
<i>Backman v. Polaroid Corp.</i> , 910 F.2d 10 (1st Cir. 1990).....	27
<i>Barrows v. Forest Labs., Inc.</i> , 742 F.2d 54 (2d Cir. 1984).....	22
<i>Bell Atl. Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	11
<i>In re Bemis Co. Sec. Litig.</i> , 512 F. Supp. 3d 518 (S.D.N.Y. 2021).....	18
<i>Born v. Quad/Graphics, Inc.</i> , 521 F. Supp. 3d 469 (S.D.N.Y. 2021).....	34, 35
<i>Bricklayers &amp; Masons Loc. Union No. 5 Ohio Pension Fund v. Transocean Ltd.</i> , 866 F. Supp. 2d 223 (S.D.N.Y. 2012).....	12

Page(s)

<i>Caiafa v. Sea Containers Ltd.</i> , 2008 WL 11516813 (S.D.N.Y. May 15, 2008), <i>aff'd</i> , 331 F. App'x 14 (2d Cir. 2009) .....	21
<i>Campo v. Sears Holding Corp.</i> , 371 F. App'x 212 (2d Cir. 2010) .....	25, 34
<i>Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC</i> , 750 F.3d 227 (2d Cir. 2014).....	34
<i>Charter Twp. of Clinton Police &amp; Fire Ret. Sys. v. KKR Fin. Holdings LLC</i> , 2010 WL 4642554 (S.D.N.Y. Nov. 17, 2010).....	20, 25
<i>City of Roseville Emps. ' Ret. Sys. v. Nokia Corp.</i> , 2011 WL 7158548 (S.D.N.Y. Sept. 6, 2011).....	16
<i>In re Citigroup, Inc. Sec. Litig.</i> , 330 F. Supp. 2d 367 (S.D.N.Y. 2004).....	26
<i>City of Pontiac Policemen's &amp; Firemen's Ret. Sys. v. UBS AG</i> , 752 F.3d 173 (2d Cir. 2014).....	26, 29
<i>In re Cosi, Inc. Sec. Litig.</i> , 379 F. Supp. 2d 580 (S.D.N.Y. 2005).....	23
<i>DCML LLC v. Danka Business Sys. PLC</i> , 2008 WL 5069528 (S.D.N.Y. Nov. 26, 2008).....	23
<i>In re Delcath Sys., Inc. Sec. Litig.</i> , 36 F. Supp. 3d 32 (S.D.N.Y. 2014) .....	18, 28
<i>DeMarco v. DepoTech Corp.</i> , 149 F. Supp. 2d 1212 (S.D. Cal. 2001).....	17
<i>Denny v. Barber</i> , 576 F.2d 465 (2d Cir. 1978).....	2
<i>ECA, Loc. 134 IBEW Jt. Pension Tr. v. JP Morgan Chase Co.</i> , 553 F.3d 187 (2d Cir. 2009).....	13, 29, 30, 35
<i>Fin. Acquisition Partners LP v. Blackwell</i> , 440 F.3d 278 (5th Cir. 2006) .....	17
<i>FindWhat Inv'r Grp. v. FindWhat.com</i> , 658 F.3d 1282 (11th Cir. 2011) .....	27

	<u>Page(s)</u>
<i>Fort Worth Emps. ' Ret. Fund v. Biovail Corp.</i> , 615 F. Supp. 2d 218 (S.D.N.Y. 2009).....	18
<i>Francisco v. Abengoa, S.A.</i> , 481 F. Supp. 3d 179 (S.D.N.Y. 2020).....	30
<i>Fries v. N. Oil &amp; Gas, Inc.</i> , 285 F. Supp. 3d 706 (S.D.N.Y. 2018).....	33
<i>Gallagher v. Abbott Labs.</i> , 269 F.3d 806 (7th Cir. 2001) .....	24
<i>Gillis v. QRX Pharma Ltd.</i> , 197 F. Supp. 3d 557 (S.D.N.Y. 2016).....	15, 27
<i>Gissin v. Endres</i> , 739 F. Supp. 2d 488 (S.D.N.Y. 2010).....	15, 20, 25
<i>Glaser v. The9, Ltd.</i> , 772 F. Supp. 2d 573 (S.D.N.Y. 2011).....	26, 34
<i>Gray v. Wesco Aircraft Holdings, Inc.</i> , 454 F. Supp. 3d 366 (S.D.N.Y. 2020), <i>aff'd</i> , 847 F. App'x 35 (2d Cir. 2021) .....	18, 22
<i>Halperin v. eBanker USA.com, Inc.</i> , 295 F.3d 352 (2d Cir. 2002).....	18
<i>IBEW Local Union No. 58 Pension Tr. Fund &amp; Annuity Fund v.</i> <i>Royal Bank of Scot. Grp., PLC</i> , 783 F.3d 383 (2d Cir. 2015).....	12
<i>Jackson v. Abernathy</i> , 960 F.3d 94 (2d Cir. 2020).....	31
<i>Janus Cap. Grp. Inc. v. First Deriv. Traders</i> , 564 U.S. 135 (2011).....	21
<i>In re JP Morgan Chase Sec. Litig.</i> , 363 F. Supp. 2d 595 (S.D.N.Y. 2005).....	21
<i>Kalnit v. Eichler</i> , 264 F.3d 131 (2d Cir. 2001).....	29, 31
<i>Lentell v. Merrill, Lynch &amp; Co.</i> , 396 F.3d 161 (2d Cir. 2005).....	22, 34

	<u>Page(s)</u>
<i>In re Lululemon Sec. Litig.</i> , 14 F. Supp. 3d 553 (S.D.N.Y. 2014).....	33
<i>Marcu v. Cheetah Mobile Inc.</i> , 2020 WL 4016645 (S.D.N.Y. July 16, 2020).....	32
<i>In re Marsh &amp; McLennan Cos. Sec. Litig.</i> , 501 F. Supp. 2d 452 (S.D.N.Y. 2006).....	21
<i>Matrixx Initiatives, Inc. v. Siracusano</i> , 563 U.S. 27 (2011).....	12
<i>McMahan &amp; Co. v. Warehouse Ent.</i> , 65 F.3d 1044 (2d Cir. 1995).....	12
<i>In re Morgan Stanley Info. Fund Sec. Litig.</i> , 592 F.3d 347 (2d Cir. 2010).....	12, 26
<i>In re N. Telecom Ltd. Sec. Litig.</i> , 116 F. Supp. 2d 446 (S.D.N.Y. 2000).....	29
<i>In re N.Y. Cmty. Bancorp, Inc. Sec. Litig.</i> , 448 F. Supp. 2d 466 (E.D.N.Y. 2006) .....	13
<i>In re Nielsen Holdings PLC Sec. Litig.</i> , 510 F. Supp. 3d 217 (S.D.N.Y. 2021).....	11, 16
<i>In re NovaGold Res. Inc. Sec. Litig.</i> , 629 F. Supp. 2d 272 (S.D.N.Y. 2009).....	16
<i>Novak v. Kasaks</i> , 216 F.3d 300 (2d Cir. 2000).....	21, 31
<i>In re NYSE Specialists Sec. Litig.</i> , 503 F.3d 89 (2d Cir. 2007).....	17, 25
<i>Oklahoma Firefighters Pension &amp; Ret. Sys. v. Xerox Corp.</i> , 300 F. Supp. 3d 551 (S.D.N.Y. 2018).....	16, 18
<i>Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund</i> , 575 U.S. 175 (2015).....	20, 29
<i>Ong v. Chipotle Mexican Grill Inc.</i> , 294 F. Supp. 3d 199 (S.D.N.Y. 2018).....	17, 25
<i>Police &amp; Fire Ret. Sys. of City of Detroit v. SafeNet, Inc.</i> , 645 F. Supp. 2d 210 (S.D.N.Y. 2009).....	12

	<u>Page(s)</u>
<i>In re PXRE Grp., Ltd., Sec. Litig.</i> , 600 F. Supp. 2d 510 (S.D.N.Y. 2009), <i>aff'd</i> , 357 F. App'x 393 (2d Cir. 2009) .....	31
<i>Ret. Bd. of Policemen's Annuity &amp; Benefit Fund v. FXCM Inc.</i> , 333 F. Supp. 3d 338 (S.D.N.Y. 2018).....	22
<i>Rombach v. Chang</i> , 355 F.3d 164 .....	11, 21
<i>In re Sanofi Sec. Litig.</i> , 87 F. Supp. 3d 510 (S.D.N.Y. 2015), <i>aff'd sub nom. Tongue v. Sanofi</i> , 816 F.3d 199 (2d Cir. 2016).....	<i>passim</i>
<i>Santa Fe Indus., Inc. v. Green</i> , 430 U.S. 462 (1977).....	33
<i>Schaffer v. Horizon Pharma PLC</i> , 2018 WL 481883 (S.D.N.Y. Jan. 18, 2018) .....	11
<i>Scott v. Gen. Motors Co.</i> , 46 F. Supp. 3d 387 (S.D.N.Y. 2014), <i>aff'd</i> , 605 F. App'x 52 (2d Cir. 2015) .....	20, 25
<i>In re Shanda Games Ltd. Sec. Litig.</i> , 2019 WL 11027710 (S.D.N.Y. Sept. 30, 2019).....	20
<i>Shields v. Citytrust Bancorp Inc.</i> , 25 F.3d 1124 (2d Cir. 1994).....	20, 25
<i>Shreiber v. Synacor</i> , 832 F. App'x 54 (2d Cir. 2020) .....	19
<i>Slayton v. Am. Express Co.</i> , 604 F.3d 758 (2d Cir. 2010).....	14, 16, 17
<i>Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.</i> , 531 F.3d 190 (2d Cir. 2008).....	31
<i>Tellabs, Inc. v. Makor Issues &amp; Rights, Ltd.</i> , 551 U.S. 308 (2007).....	4, 13, 29
<i>In re Time Warner Inc. Sec. Litig.</i> , 9 F.3d 259 (2d Cir. 1993).....	16

	<u>Page(s)</u>
<i>Tongue v. Sanofi</i> , 816 F.3d 199 (2d Cir. 2016).....	4, 14, 20
<i>Total Equity Cap., LLC v. Flurry, Inc.</i> , 2016 WL 3093993 (S.D.N.Y. June 1, 2016) .....	31
<i>Tyler v. Liz Claiborne, Inc.</i> , 814 F. Supp. 2d 323 (S.D.N.Y. 2011).....	32
<i>W. Palm Beach Firefighters’ Pension Fund v. Conagra Brands, Inc.</i> , 495 F. Supp. 3d 622 (N.D. Ill. 2020) .....	16
<i>Zagami v. Cellceutix Corp.</i> , 2016 WL 3199531 (S.D.N.Y. June 8, 2016) .....	21

#### Statutes, Regulations, and Rules

15 U.S.C. § 77b(a)(8).....	21
15 U.S.C. § 77b(a)(10).....	21
15 U.S.C. § 77k.....	10, 11, 21
15 U.S.C. § 77l(a)(2).....	10, 12, 20, 21
15 U.S.C. § 77o.....	10, 13, 35
15 U.S.C. §§ 77z-2(i)(1) .....	14
15 U.S.C. § 77z-2(c) .....	4, 14, 16
15 U.S.C. § 78j(b).....	10, 11, 12
15 U.S.C. § 78n(a) .....	10, 12, 13, 22
15 U.S.C. § 78u-4(b)(1) .....	13, 23
15 U.S.C. § 78u-4(b)(2) .....	13, 29
15 U.S.C. § 78u-4(b)(4) .....	22, 34
15 U.S.C. § 78t(a).....	10, 13, 35
15 U.S.C. § 78u-5(c).....	4, 14, 16, 27
15 U.S.C. § 78u-5(e).....	28

	<u>Page(s)</u>
15 U.S.C. §§ 78u-5(i)(1) .....	15, 27
17 C.F.R. § 240.10b-5 .....	10, 11, 12
17 C.F.R. § 240.14a-9 .....	10
Fed. R. Civ. P. 12(b)(6) .....	1, 4, 11
Fed. R. Civ. P. 9(b) .....	11, 21
Fed. R. Evid. 201(b) .....	8

Defendants respectfully submit this memorandum of law in support of their joint motion to dismiss the complaint pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure.<sup>1</sup>

### **PRELIMINARY STATEMENT**

Plaintiffs assert claims under the federal securities laws on behalf of a putative class of acquirors of contingent value rights (“CVRs”) issued in connection with the 2019 merger between Bristol-Myers Squibb Company (“BMS”) and Celgene Corporation. Each CVR provided a contingent right to receive a \$9 payment from BMS if, but only if, the U.S. Food and Drug Administration (“FDA”) approved applications for three different Celgene product candidates by contractual milestone dates. If the FDA denied any of those applications or approved one late, “*even by a single day*,” the CVRs would expire valueless. Compl. ¶ 81. The FDA approved all three applications. But one – for a cutting-edge cancer therapy called liso-cel – was approved 36 days too late for CVR holders to receive payment. *Id.* ¶ 36.

The complaint attempts to transform plaintiffs’ disappointment about these events into federal securities claims. Plaintiffs allege that CVR-related disclosures over a nearly two-year period were false because, from the time of the Celgene merger agreement in early 2019, BMS had no intention to make payment on the CVRs and secretly “slow-roll[ed] the FDA application process . . . so that it would miss at least one FDA milestone[.]” Compl. ¶ 159; *id.* ¶¶ 170, 172, 174, 176, 177, 180, 182, 184, 187, 189, 190, 192, 194, 196, 199, 203, 206.

The complaint does not offer a single allegation of contemporaneous fact to support this outlandish conspiracy theory. Plaintiffs acknowledge the FDA approved all three applications,

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<sup>1</sup> In addition to BMS, the defendants are Peter J. Arduini, Charles Bancroft, Robert Bertolini, Giovanni Caforio, David V. Elkins, Matthew W. Emmens, Michael Grobstein, Samit Hirawat, Alan J. Lacy, Dinesh C. Paliwal, Theodore R. Samuels, Karen M. Santiago, Vicki L. Sato, Gerald L. Storch, and Karen H. Vousden.

largely within the timeframe contemplated at the time of the Celgene merger agreement years earlier. *Id.* ¶¶ 95, 129, 134. Plaintiffs’ assertion that BMS manipulated the FDA approval process to ensure liso-cel was approved, but not until 36 days after its milestone date, defies common sense. They ask the Court to take implausible inferential leaps based on setbacks in the liso-cel approval process that occurred long *after* most of the challenged disclosures, and amidst the worst pandemic in over a century.

The federal securities laws do not provide a cause of action for fraud by hindsight, *Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978), but even plaintiffs’ hindsight allegations conflict with their claims. The complaint acknowledges that BMS completed the liso-cel application only weeks after the merger closing, *id.* ¶ 95; and the FDA granted it “Priority Review” soon thereafter – an admittedly “positive step,” *id.* ¶ 98. When the FDA later determined there had been a “major amendment” to the application, thus extending its own deadline by three months, that *still* left six weeks’ leeway before the contractual milestone date. *Id.* ¶ 102. “[E]ven after” the delay, analysts predicted timely approval “was more likely than not.” *Id.*

But approval required FDA inspections of two different manufacturing facilities, one of which the FDA had never inspected and was operated by Lonza Group AG (“Lonza”), not by BMS. *Id.* ¶¶ 103, 115. Months after the Celgene merger closed, in March 2020, the COVID-19 pandemic forced the FDA to curtail facility inspections; BMS later warned that this decision “could impact” the inspections needed for liso-cel approval. *Id.* ¶ 188. Yet BMS continued to work “very actively” with the FDA to schedule them. *See id.* ¶ 195, 202. Ultimately, due to pandemic-related restrictions, the FDA could not inspect the Lonza facility until early December. *Id.* ¶¶ 202, 204. BMS responded within days to the FDA’s ensuing inspection report – still well

before the December 31, 2020 milestone date. *Id.* ¶¶ 116, 126. Liso-cel was approved soon thereafter, but too late to permit payment under the CVRs. *Id.* ¶ 129.

Plaintiffs’ allegations from “confidential witnesses” confirm that BMS was working hard behind the scenes to obtain approval throughout this period. BMS allegedly conducted a pre-inspection mock audit of the Lonza facility, formed a “task force” when the audit identified issues, held calls with Lonza teams “two to three times per week,” and even “berated” Lonza employees when things “were not going well despite how much money [BMS] was spending at Lonza.” *Id.* ¶ 120. None of these allegations is consistent with plaintiffs’ assertion that BMS was determined to scuttle timely FDA approval. Indeed, the allegations further support the inference that challenged statements made during this period were true when made.

Putative class members understood from the outset that the value of the CVRs was “speculative, and the CVRs may ultimately have no value.” Compl. ¶ 163. The joint proxy statement for the Celgene merger, issued in February 2019, warned of the “uncertainty regarding the fair market value of the CVR and whether any payment will ultimately be realized[.]” Proxy Stmt. at 4 (Clarke Decl., Exh. 1); *see id.* at 39. At the time of the merger agreement, BMS itself estimated only a 45% probability that the CVR contingencies would be met – which it disclosed – and the proxy statement provided a risk-weighted estimated value of \$3.75 per CVR – far less than the \$9 per CVR that *might* be paid. *Id.* at 50, 68, 157; *see* Compl. ¶¶ 158, 163. During the thirteen months of the “class period” *after* the merger closed, BMS reiterated warnings about the risk of non-payment. *See, e.g., id.* ¶ 198 (quoting Form 10-Q).

Unfortunately, the risks ultimately came to fruition. When the FDA did not issue its approval decision for the liso-cel application by December 31, 2020, the CVRs “expire[d] without value,” as BMS had warned they might. Compl. ¶ 188. Given these warnings and for other

reasons, most of the challenged statements are protected by the statutory safe harbor for forward-looking statements. *See* 15 U.S.C. §§ 77z-2(c), 78u-5(c). But whether they were forward-looking or not, plaintiffs also have failed to plausibly allege that any challenged statement was false when made. Nor does the complaint plead facts that would support the required “strong inference” of scienter for plaintiffs’ fraud claims or, for all but their Securities Act claims (for which the burden is allocated to defendants), loss causation.

For all of those reasons, discussed in detail below, plaintiffs have not stated an actionable claim under any of the provisions they invoke. The complaint should be dismissed in its entirety.

### **BACKGROUND**<sup>2</sup>

#### **A. The Parties**

BMS is a global biopharmaceutical company whose mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases. Compl. ¶ 44. The individual defendants are or were BMS officers or members of its board of directors. *Id.* ¶¶ 45-63.

Mangrove Partners Master Fund, Ltd. was appointed lead plaintiff under the Private Securities Litigation Reform Act of 1995 (“PSLRA”) in an order entered on December 22, 2021. [ECF No. 91] It allegedly purchased CVRs in the open market between March and December 2020. [ECF No. 63-1] Plaintiffs SM Merger/Arbitrage, L.P., SM Investors, L.P., SM Investors II, L.P., and Ehab Khalil allege they were Celgene stockholders who exchanged their shares for

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<sup>2</sup> As Rule 12(b)(6) requires, well-pleaded factual allegations are assumed to be true solely for the purpose of this motion to dismiss. *Tongue v. Sanofi*, 816 F.3d 199, 209 (2d Cir. 2016). “The Court may also ‘consider any written instrument attached to the complaint, statements or documents incorporated into the complaint by reference, legally required public disclosure documents filed with the SEC, and documents possessed by or known to the plaintiff upon which it relied in bringing the suit.’” *Id.* (quoting *ATSI Commc’ns Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 98 (2d Cir. 2007)); *see Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007). Cited exhibits are attached to the accompanying Declaration of John J. Clarke, Jr. dated April 8, 2022 (“Clarke Decl.”).

merger consideration, including CVRs, in the merger with BMS. Compl. ¶¶ 40-43.

### **B. The Celgene Merger and the CVRs**

BMS issued the CVRs on November 20, 2019 in connection with the closing of its merger with Celgene. Compl. ¶¶ 1, 17. Pursuant to the merger agreement, which the parties entered into as of January 2, 2019, Celgene stockholders received one share of BMS common stock, \$50.00 in cash, and one CVR in exchange for each outstanding share of Celgene common stock. *Id.* ¶ 85.<sup>3</sup>

The CVRs provided holders a contingent right to receive payment of \$9 per CVR, but only if applications for three separate Celgene product candidates were approved by the FDA by contractual milestone dates: (i) liso-cel, a CAR-T therapy that is a treatment for large B-cell lymphoma, by December 31, 2020; (ii) ozanimod, a treatment for relapsing multiple sclerosis, also by December 31, 2020; and (iii) ide-cel, a CAR-T therapy for refractory multiple myeloma, by March 31, 2021. *Id.* ¶ 81. If the FDA failed to approve even one of the three applications by its milestone date, then CVR holders would not be entitled to any payment. *Id.* ¶¶ 1, 81. The FDA was not a party to the agreements.

On February 22, 2019, BMS and Celgene filed a joint proxy statement / prospectus seeking approval from their respective stockholders for the proposed transaction. *Id.* ¶ 86. The joint proxy statement / prospectus was deemed to be a part of a Form S-4 registration statement filed by BMS on February 1, 2019. *See id.* Among a number of risks specific to the CVRs, the proxy statement warned Celgene stockholders that:

#### **You may not receive any payment on the CVRs.**

Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the

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<sup>3</sup> The proxy statement disclosed that “the cash and stock components of the merger consideration represented approximately \$99.37 in value per share of Celgene common stock” (based on the January 31, 2019 closing price of BMS stock). Proxy Stmt. at 1.

time periods specified in the CVR agreement. If the CVR milestone . . . is not achieved for any reason within the time periods specified in the CVR agreement, no payment will be made under the CVRs, and the CVRs will expire valueless. Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value. . . .

Proxy Stmt. at 50. The proxy statement also disclosed BMS management’s estimate, in evaluating the merger consideration to be paid, that there was a 45% probability that “the three FDA approvals required to trigger the \$9 payment under the CVR agreement” would be obtained in time. Compl. ¶ 158 (quoting Proxy Stmt. at 157). Elsewhere, the proxy statement included an estimated, risk-weighted present value for each CVR of \$3.75 after taking into account “the probability of achieving all three necessary approvals[.]” Proxy Stmt. at 68.

BMS and Celgene stockholders approved the merger on April 12, 2019. Compl. ¶¶ 17, 90. The closing occurred on November 20, 2019, and the CVR Agreement setting forth the terms of the CVRs became effective then. *Id.* ¶¶ 17, 92. The CVRs began trading on the New York Stock Exchange thereafter. *Id.* ¶ 36.

### **C. The FDA Applications**

Plaintiffs allege that BMS never intended to make payment on the CVRs or to use “diligent efforts” to obtain FDA approval of all three applications by the contractual milestone dates. Instead, according to the complaint, BMS “slow roll[ed] the FDA application process . . . so that it would miss at least one FDA milestone and avoid making the \$9 CVR payment worth \$6.4 billion.” Compl. ¶ 159; *id.* ¶¶ 170-206. The biologics license application (“BLA”) for FDA approval of liso-cel is the focus of plaintiffs’ theory.

Liso-cel is a CAR-T therapy – a chimeric antigen receptor immunotherapy designed to train a patient’s own T-cells to recognize and attack cancer cells. It is used to treat patients with large B-cell lymphoma. Compl. ¶ 11. Early studies indicated liso-cel had better efficacy and safety than two earlier CAR-T therapies. *Id.* ¶ 69. As with other CAR-T therapies, production of

liso-cel is complex. T-cells are extracted from a patient’s blood and genetically modified before being reinfused into the patient with a viral vector “for the purpose of recognizing and destroying cancer cells.” *Id.* ¶ 67.

In 2018, Celgene took over the development of liso-cel when it acquired Juno Therapeutics. *Id.* ¶¶ 67-68. Until the merger with BMS closed on November 20, 2019, Celgene remained responsible for the liso-cel application process and communications with the FDA about it. Celgene filed the first two of three modules for the rolling application before the merger with BMS closed. *Id.* ¶¶ 91, 95. On December 18, 2019, less than a month after the closing of the merger, BMS filed the last module, which addressed Chemistry, Manufacturing, and Controls (“CMC”). *Id.* ¶ 96.<sup>4</sup>

On February 13, 2020, *after* the FDA completed its initial review, it granted “Priority Review” to the liso-cel application. *Id.* ¶ 98. This meant the FDA’s deadline to act was “four months shorter than its typical review time” under the Prescription Drug User Fee Act of 1992 (“PDUFA”). *Id.* ¶ 97. Securities analysts declared this “‘another positive step’ for CVR holders, because it ‘*could even allow for a three-month delay*’” and still permit liso-cel to be approved before its milestone date. *Id.* ¶ 98 (emphasis added).

On April 15, 2020, BMS submitted information in response to an FDA request for supporting “data on assays and validation” relating to the CMC module. *Id.* ¶ 100. The FDA allegedly concluded weeks later that the submission constituted a “major amendment” to the BLA, which “automatically triggered [a] three-month extension of the PDUFA date” until

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<sup>4</sup> As a breakthrough therapy, *see* Compl. ¶ 2, liso-cel qualified for “rolling review” by the FDA, which reviewed completed portions before the application was fully submitted. *See* FDA Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics, 79 Fed. Reg. 31117 (May 30, 2014).

November 16, 2020 – still “weeks *before* the December 31, 2020” milestone date. *Id.* ¶ 102 (emphasis added). BMS promptly disclosed this development in a press release on May 6, 2020. *Id.* ¶ 175.

During the same general period, COVID-19 was declared a global pandemic, the pandemic was declared a national emergency, and pandemic-related operating restrictions began to significantly impact the FDA. FDA Statement, “Coronavirus (COVID-19) Update: FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections,” Mar. 18, 2020 [[bit.ly/3zjHM1u](https://bit.ly/3zjHM1u)].<sup>5</sup>

Two manufacturing facilities were to be used for production of liso-cel: T-cells would be processed at a Juno Therapeutics facility in Bothell, Washington and the viral vector would be produced at a Lonza facility in Houston, Texas. *Id.* ¶¶ 103, 191. The FDA required both facilities to be inspected before it would approve liso-cel. *Id.* The Lonza facility had not been inspected by the FDA before. *Id.* ¶ 115. Plaintiffs allege that BMS failed adequately to prepare the two facilities for their FDA inspections. Compl. ¶¶ 103-26. Plaintiffs acknowledge that pandemic travel restrictions delayed the inspections until October 2020 for the Juno facility and early December 2020 for the Lonza facility, the latter of these only weeks before the liso-cel milestone date. *See id.* ¶¶ 107, 195, 197, 204. Plaintiffs admit that both inspections were completed, and BMS addressed the FDA’s observations, *before* the December 31, 2020 milestone date. *Id.* ¶¶ 116, 126.

On January 1, 2021, BMS issued a press release reporting that the FDA had not issued a decision on the liso-cel application by the milestone date the previous day. As a result, the press release explained, “the CVR Agreement ha[d] automatically terminated in accordance with its

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<sup>5</sup> The Court may take judicial notice of these developments, which are generally known and not subject to reasonable dispute. Fed. R. Evid. 201(b); *see 100 Orchard St., LLC v. Travelers Indem. Ins. Co. of Am.*, 2021 WL 2333244, at \*1 n. 4 (S.D.N.Y. June 8, 2021) (Furman, J.).

terms, the [CVRs] [would] no longer trade on the NYSE, and the CVRs [we]re no longer eligible for payment.” *Id.* ¶ 128. The FDA approved liso-cel five weeks later, on February 5, 2021. *Id.* ¶¶ 33, 216.

Now in hindsight, the complaint alleges that the FDA’s “major amendment” decision was due to the intentional omission of “basic data” from the CMC module. *Id.* ¶ 99. In June 2020, however, a senior FDA official acknowledged the agency had been inconsistent in its review of cell therapy applications, such as those for liso-cel and ide-cel. *See* Exh. 3, “Top US FDA Official Says New ‘Playbook’ Needed for CMC Reviews of Gene Therapy Products,” *The Pink Sheet*, June 18, 2020 (“I know that someone out there will say, ‘we had two different CMC reviewers and two different pieces of advice.’ I am not going to argue with that. That is an issue here.”).

Plaintiffs further allege that delaying FDA approval of ide-cel was BMS’s undisclosed back-up plan to avoid the CVR payment. Compl. ¶¶ 132-35. They assert the ide-cel application “had a materially deficient” CMC module, “which prompted the FDA to issue a Refuse to File letter on May 13, 2020[.]” *Id.* ¶ 132. But the complaint admits that the FDA approved a resubmitted application for ide-cel *before* its March 31, 2021 milestone date. *Id.* ¶ 135. The FDA also approved ozanimod before its milestone date. *Id.* ¶ 95.

According to the complaint, the market price for CVRs declined between May 6, 2020 and December 31, 2020 when BMS reported “various delays in the [FDA] approval process” for liso-cel; plaintiffs allege that when the liso-cel milestone date passed without an FDA approval decision “the remaining artificial inflation dissipated” from the market price of the CVRs. Compl. ¶¶ 224-29.

#### **D. Challenged Statements**

Plaintiffs assert claims based on two categories of alleged misstatements: (i) disclosures in the joint proxy statement / prospectus dated February 22, 2019, which was made a part of a

Form S-4 registration statement filed by BMS three weeks earlier; and (ii) disclosures in periodic reports, press releases, earnings calls, and investor presentations from the November 20, 2019 closing of the Celgene merger through the liso-cel milestone date on December 31, 2020. A table listing the challenged statements is attached as Appendix 1.

Plaintiffs allege that all of the challenged statements were false or misleading because they failed to disclose that BMS allegedly intended to “slow-roll” the FDA approval “process for [l]iso-cel . . . so that they would miss at least one FDA milestone and avoid making the \$9 CVR payment.” *See* Compl. ¶¶ 159-206. In an effort to substantiate this unfounded allegation, plaintiffs include allegations from eight “confidential witnesses,” only one of whom is alleged to have been a BMS employee. None of the “confidential witness” allegations support plaintiffs’ fraud theory. *See id.* ¶¶ 101, 106, 120-23. Plaintiffs also rely on hindsight criticisms expressed by a purported “FDA Biologics Expert” with no apparent personal knowledge of relevant events. *See, e.g.*, Compl. ¶¶ 4 & n.1, 99-101, 108-16.

#### **E. Plaintiffs’ Claims**

Plaintiffs assert claims on behalf of a putative class consisting of all persons who purchased or otherwise acquired CVRs during the alleged “class period,” from November 20, 2019 through December 31, 2020. Compl. at 1; *id.* ¶ 235. The complaint asserts claims under sections 11 and 12(a)(2) of the Securities Act of 1933, 15 U.S.C. §§ 77k, 77l(a)(2), sections 10(b) and 14(a) of the Securities Exchange Act of 1934, and Rules 10b-5 and 14a-9 promulgated thereunder, 15 U.S.C. §§ 78j(b), 78n(a); 17 C.F.R. §§ 240.10b-5, 240.14a-9. Compl. ¶¶ 243-54, 262-82. Plaintiffs also assert “controlling person” claims under section 15 of the Securities Act and section 20(a) of the Exchange Act, 15 U.S.C. §§ 77o, 78t(a); Compl. ¶¶ 255-61, 283-91.<sup>6</sup>

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<sup>6</sup> The claim under § 14(a) of the Exchange Act is asserted against BMS and the members of its board of directors at the time of the joint proxy statement / prospectus. Compl. ¶¶ 49-60,

## **LEGAL STANDARDS**

### **A. Motions to Dismiss**

To avoid dismissal under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A facially plausible claim is one that enables the court “to draw the reasonable inference that the defendant is liable for the misconduct alleged.” *Iqbal*, 556 U.S. at 678. The plaintiff “must allege sufficient facts to show ‘more than a sheer possibility that a defendant has acted unlawfully.’” *In re Nielsen Holdings PLC Sec. Litig.*, 510 F. Supp. 3d 217, 224-25 (S.D.N.Y. 2021) (Furman, J.) (quoting *Iqbal*, 556 U.S. at 678). “If [p]laintiffs have not ‘nudged their claims across the line from conceivable to plausible, [those claims] must be dismissed.’” *Schaffer v. Horizon Pharma PLC*, 2018 WL 481883, at \*2 (S.D.N.Y. Jan. 18, 2018) (Furman, J.) (quoting *Twombly*, 550 U.S. at 570).

Where a claim is based on, or “sounds in” fraud, Rule 9(b) further requires the complaint to “(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent.” *Rombach v. Chang*, 355 F.3d 164, 170-71 (citation omitted); *see* Fed. R. Civ. P. 9(b).

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248-54. The claim under § 11(a) of the Securities Act is asserted against the same defendants as well as former chief financial officer Charles Bancroft and controller Karen Santiago, who each allegedly signed the registration statement. *Id.* ¶¶ 49-63, 262-71. The claim under § 12(a)(2) of the Securities Act is asserted solely against BMS. *Id.* ¶¶ 272-82. The claims under § 10(b) and Rule 10b-5 are asserted against BMS, its chief executive officer Giovanni Caforio, M.D., its chief financial officer David V. Elkins, and its chief medical officer Samit Hirawat, M.D. *Id.* ¶¶ 45-48, 243-47. Mr. Elkins and Dr. Hirawat are not named in the claim under § 15, and Mr. Bancroft and Ms. Santiago are not named in the claim under § 20(a). *Id.* ¶¶ 255-61, 283-91.

## **B. Elements of the Causes of Action**

A plaintiff asserting a claim under section 11 of the Securities Act must plausibly allege that a “registration statement contained an untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading.” *In re Morgan Stanley Info. Fund Sec. Litig.*, 592 F.3d 347, 358-59 (2d Cir. 2010); *see also McMahan & Co. v. Warehouse Ent.*, 65 F.3d 1044, 1047 (2d Cir. 1995). Subject to additional limitations on who can sue or be sued, claims under section 12(a)(2) are “essentially the same,” except that the provision “applies to prospectuses, while [§] 11 applies to registration statements.” *Police & Fire Ret. Sys. of City of Detroit v. SafeNet, Inc.*, 645 F. Supp. 2d 210, 226 (S.D.N.Y. 2009); *see Morgan Stanley Info. Fund*, 592 F.3d at 359.

To state a claim under section 14(a) of the Exchange Act, a plaintiff must plausibly allege that: “a proxy statement contained a material misrepresentation or omission, which (2) caused plaintiffs’ injury, and (3) that the proxy solicitation itself, rather than the particular defect in the solicitation materials, was an essential link in the accomplishment of the transaction.” *Bricklayers & Masons Loc. Union No. 5 Ohio Pension Fund v. Transocean Ltd.*, 866 F. Supp. 2d 223, 238 (S.D.N.Y. 2012). The complaint must “specify each statement alleged to have been misleading” and “the reason or reasons why” it was misleading. 15 U.S.C. § 78u-4(b)(1).

To state a claim for securities fraud under section 10(b) and Rule 10b-5, plaintiffs must allege “(1) a material misrepresentation or omission by the defendant; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; (5) economic loss; and (6) loss causation.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37-38 (2011); *see IBEW Local Union No. 58 Pension Tr. Fund & Annuity Fund v. Royal Bank of Scot. Grp., PLC*, 783 F.3d 383, 389 (2d Cir. 2015).

In addition to specifying allegedly fraudulent statements and the reasons they were false or misleading, 15 U.S.C. § 78u-4(b)(1), the PSLRA requires a securities fraud complaint to “state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind,” that is, scienter. 15 U.S.C. § 78u-4(b)(2); *ATSI*, 493 F.3d at 99. The inference of scienter “must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 324.

Finally, a claim for “controlling person” liability under section 15 of the Securities Act or section 20(a) of the Exchange Act requires “a primary violation” and control of the primary violator by defendants. *ECA, Loc. 134 IBEW Jt. Pension Tr. v. JP Morgan Chase Co.*, 553 F.3d 187, 206-07 (2d Cir. 2009); *ATSI*, 493 F.3d at 108. Where securities fraud is the underlying violation, the plaintiff must plausibly allege that the controlling person “was, in some meaningful sense, a culpable participant in the controlled person’s fraud.” *ATSI*, 498 F.3d at 108.

## **ARGUMENT**

### **I. PLAINTIFFS HAVE NOT PLAUSIBLY ALLEGED ANY SECURITIES CLAIM BASED ON THE JOINT PROXY STATEMENT / PROSPECTUS.**

All of plaintiffs’ Securities Act claims, and their claims under Exchange Act § 14(a), are based on the same challenged disclosures in the joint proxy statement / prospectus issued on February 22, 2019, which also was part of a registration statement. Compl. ¶¶ 156-67, 249, 263, 277. The claims can be evaluated together, *In re N.Y. Cmty. Bancorp, Inc. Sec. Litig.*, 448 F. Supp. 2d 466, 477, 484 (E.D.N.Y. 2006), and they are equally untenable.

#### **A. The Complaint Does Not Allege a Material Misstatement or Omission in the Joint Proxy Statement / Prospectus.**

The complaint alleges the joint proxy statement / prospectus was misleading in disclosing that liso-cel and a number of other late-stage Celgene product candidates were “expected to launch in 2019 and 2020,” that BMS estimated a 45% probability of achieving the CVR milestones, that

BMS intended to use “diligent efforts” to achieve the milestones, and that the value of the CVRs was “speculative” and “unknown.” Compl. ¶¶ 158, 160-61, 163-64 (Statements 1-4). These disclosures allegedly were false because BMS had no intention “to use diligent efforts” and instead “intended to slow-roll the FDA application process” to “avoid making the \$9 CVR payment[.]” Compl. ¶¶ 159, 162, 165. Plaintiffs have not alleged any actionable misstatement for these claims.

### 1. The PSLRA Safe Harbor Bars the Claims.

The challenged disclosures were forward-looking statements for which defendants are protected from liability by the safe harbor added by the PSLRA, which bars liability for claims based on any forward-looking statement that is made without “actual knowledge that it was false or misleading,” is “accompanied by meaningful cautionary language,” or is immaterial. 15 U.S.C. § 77z-2(c)(1); 15 U.S.C. § 78u-5(c)(1); *see Slayton v. Am. Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010). The provision is substantially the same in both the Securities Act and the Exchange Act. *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 529 (S.D.N.Y. 2015), *aff’d sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016).

Forward Looking Statements. All of the challenged disclosures were forward-looking statements – “statements whose truth cannot be ascertained until sometime after the time they are made[.]” *In re Aegon N.V. Sec. Litig.*, 2004 WL 1415973, at \*12 (S.D.N.Y. June 23, 2004). The joint proxy statement / prospectus expressly identified its disclosures concerning “the timing and probability of a payment pursuant to the [CVRs]” as forward-looking and warned that those statements were “*only predictions* and involve known and unknown risks and uncertainties” and were “based upon management’s then-current views and assumptions regarding future events and operating performance . . . .” Proxy Stmt. at 80, 81 (emphasis added).<sup>7</sup>

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<sup>7</sup> The challenged disclosures were: (i) “a statement containing a projection of revenues, income . . . , or other financial items;” (ii) “a statement of the plans of management for future

As courts have recognized repeatedly, this kind of statement is “classically forward-looking.” *Sanofi*, 87 F. Supp. 3d at 535. For example, in dismissing securities claims on behalf of a putative class of CVR investors in *Sanofi*, the district court concluded that very similar statements about the timing and prospects for FDA approval of Lemtrada were forward-looking. *Id.* at 521, 535. Other courts have reached the same conclusion. *See, e.g., Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at \*10 (S.D.N.Y. Apr. 28, 2020) (statements that defendants expected FDA approval and intended to launch product soon thereafter were forward-looking); *Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 585 (S.D.N.Y. 2016) (statements that issuer “met the basic requirements for clinical data to enable NDA filing” and “was looking forward to the regulatory approval process that may enable product sales in 2012” were “classically forward-looking”).

Plaintiffs are mistaken in asserting that the challenged proxy statement disclosures “relate[d] to then-existing facts and conditions.” Compl. ¶ 241; *see Gissin v. Endres*, 739 F. Supp. 2d 488, 505-06 (S.D.N.Y. 2010) (rejecting attempt to avoid safe harbor based on contention that forward-looking statements were based on “prior and present” facts). The disclosures did not concern then-existing “facts.” Celgene remained in charge of the FDA approval process (as it would be until the merger closed); the liso-cel and ide-cel applications had not been filed; and the CVR milestone dates were two years in the future. *Id.* ¶¶ 81, 91, 95, 96, 103-26. The CVR Agreement, including its “diligent efforts” provision, would not even become *effective* for nine more months. *Id.* ¶ 92. The predictions were, of course, made in the present, but “[a]ny projection or forward-looking statement necessarily has its basis in current conditions[.]” That “does not

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operations, including plans or objectives relating to the products or services of the issuer[],” or (iii) a “statement of the assumptions underlying or relating to” the foregoing. 15 U.S.C. §§ 77z-2(i)(1)(A), (B), (D); 15 U.S.C. §§ 78u-5(i)(1)(A), (B), (D).

change the fact that it uses those current conditions to make some kind of prediction about the future.” *In re NovaGold Res. Inc. Sec. Litig.*, 629 F. Supp. 2d 272, 292 (S.D.N.Y. 2009).

No Knowledge of Alleged Falsity. The complaint does not plausibly allege that either BMS or any of the individual defendants had actual knowledge at the time of the joint proxy statement / prospectus that any of the challenged disclosures was false. 15 U.S.C. § 77z-2(c)(1); 15 U.S.C. § 78u-5(c)(1). None was. The complaint does not include any allegation of contemporaneous fact to support plaintiffs’ assertion that the defendants knew BMS “was not going to use diligent efforts to meet” the CVR milestones and “intended to slow-roll the FDA application process . . . .” Compl. ¶¶ 159, 162, 165.

Nor is it sufficient for plaintiffs to argue that knowledge of falsity should be inferred from setbacks in the FDA approval process more than a year later. *Id.* ¶¶ 99-101, 103-16. This is paradigmatic fraud by hindsight. *Nielsen*, 510 F. Supp. 3d at 231 (complaint “fail[ed] to allege any specific, contemporaneous reports or statements showing [d]efendants did not believe their projections when made”); *see City of Roseville Emps.’ Ret. Sys. v. Nokia Corp.*, 2011 WL 7158548, at \*5 (S.D.N.Y. Sept. 6, 2011) (factual allegations did “not demonstrate that either risk had already transpired” or support inference that defendants “did not have these favorable opinions” or that opinions “were without any basis in fact”) (quoting *In re Time Warner Inc. Sec. Litig.*, 9 F.3d 259, 266 (2d Cir. 1993)). Plaintiffs’ own allegations show that BMS responded to setbacks, when they arose, by addressing FDA concerns quickly so that liso-cel and ide-cel might still be approved before their respective milestone dates. *See* Compl. ¶¶ 113, 114, 116, 126, 132, 135.<sup>8</sup>

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<sup>8</sup> “The scienter requirement for forward-looking statements – actual knowledge – is ‘stricter than for statements of current fact’ because liability for such statements requires ‘proof of knowing falsity.’” *Oklahoma Firefighters Pension & Ret. Sys. v. Xerox Corp.*, 300 F. Supp. 3d 551, 568 (S.D.N.Y. 2018) (quoting *Slayton*, 604 F.3d at 773); *see W. Palm Beach Firefighters’ Pension Fund v. Conagra Brands, Inc.*, 495 F. Supp. 3d 622, 667 (N.D. Ill. 2020) (“[A] claim

Alleged hindsight criticism from an unidentified “FDA Biologics Expert” hired by plaintiffs in an attempt to add weight to their unsubstantiated allegations do not alter the analysis. Compl. ¶¶ 99-101, 108-16, 120-26. Courts regularly reject such allegations. *Ong v. Chipotle Mexican Grill Inc.*, 294 F. Supp. 3d 199, 223-24 (S.D.N.Y. 2018) (refusing to consider opinions of food safety expert in deciding motion to dismiss securities fraud complaint); *see In re NYSE Specialists Sec. Litig.*, 503 F.3d 89, 95 (2d Cir. 2007) (“[l]egal conclusions, deductions or opinions couched as factual allegations” are not entitled to “a presumption of truthfulness”); *Fin. Acquisition Partners LP v. Blackwell*, 440 F.3d 278, 285-86 (5th Cir. 2006) (“opinions cannot substitute for facts under the PSLRA”); *DeMarco v. DepoTech Corp.*, 149 F. Supp. 2d 1212, 1220-22 (S.D. Cal. 2001) (to permit allegations based on expert opinions would raise “a myriad of complex evidentiary issues not generally capable of resolution at the pleading stage”).

Accompanied by Cautionary Language. The safe harbor also applies because the challenged forward-looking statements were accompanied by meaningful cautionary language. Plaintiffs admit the joint proxy statement / prospectus expressly warned about risks associated with the CVRs, including the risk that the milestones might not be met and the CVRs “ultimately may have no value.” Compl. ¶ 163; *see* Proxy Stmt. at 50 (if CVR milestones are “not achieved **for any reason** within the time periods specified . . . no payment will be made under the CVRs, and the CVRs **will expire valueless.**”) (emphasis added).

There can be no serious contention that this warning was “boilerplate” or failed to convey “substantive information.” *Slayton*, 604 F.3d at 772. The cautionary language “expressly warn[ed] of” and “directly relat[ed] to” the risk that allegedly “brought about plaintiffs’ loss.”

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under the Securities Act involving forward-looking statements now appears to require, for all practical purposes, proof of scienter.”).

*Halperin v. eBanker USA.com, Inc.*, 295 F.3d 352, 359 (2d Cir. 2002); *see Xerox Corp.*, 300 F. Supp. 3d at 567 (“meaningful” cautionary language “convey[s] substantive information about factors that realistically could cause results to differ materially”); *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 32, 33 (S.D.N.Y. 2014) (courts must “first ‘identify the allegedly undisclosed risk’” and then review disclosures “to determine if a reasonable investor could have been misled” into thinking that risk “did not actually exist”).

As in *Sanofi*, the risk factor plaintiffs have quoted in the complaint “explicitly identifie[d] the salient risk[.]” *Sanofi*, 87 F. Supp. 3d at 536. In this case, that risk was that the CVRs could expire valueless if, *for any reason*, the FDA did not approve any of three applications by its milestone date. The cautionary “statements conveyed substantive information about the risk that ultimately materialized[.]” and that protects defendants from liability. *Id.*; *see Delcath*, 36 F. Supp. 3d at 334 (warning “adequately disclosed the possibility of a risk that materialized when the FDA denied approval”); *Fort Worth Emps.’ Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 232-33 (S.D.N.Y. 2009) (warning concerning “the difficulty of predicting” regulatory approvals satisfied safe harbor).

Finally, plaintiffs’ allegation that the cautionary language omitted that BMS “intended to slow-roll the FDA application process,” Compl. ¶ 165, not only is conclusory and therefore entitled to no deference but also improperly “conflates the actual knowledge and meaningful cautionary language prongs” of the safe harbor. *In re Bemis Co. Sec. Litig.*, 512 F. Supp. 3d 518, 534 (S.D.N.Y. 2021) (quoting *Gray v. Wesco Aircraft Holdings, Inc.*, 454 F. Supp. 3d 366, 394 (S.D.N.Y. 2020), *aff’d*, 847 F. App’x 35 (2d Cir. 2021)). That is “contrary to the disjunctive nature of the safe harbor elements.” *Gray*, 454 F. Supp. 3d at 394. “Either cautionary language or an absence of knowledge is alone sufficient to trigger the safe harbor.” *Id.* at 395.

## 2. Plaintiffs Do Not Otherwise Allege an Actionable Misstatement.

Beyond application of the safe harbor, plaintiffs’ proxy statement-based claims fail to plausibly allege any material misstatement. There is no basis to infer that the challenged disclosures were false. They include an accurate description of the CVRs, Compl. ¶ 160 (Statement 2); an accurate quotation of the “diligent efforts” definition in the CVR Agreement, ¶ 161 (Statement 3); excerpts from the risk factor warning that “the CVRs may ultimately have no value,” *id.* ¶ 163 (Statement 4); and an explanation that Celgene stockholders would “not be able to determine the market value of the merger consideration” when they voted due to the future contingencies applicable to the CVRs, *id.* ¶ 164 (Statement 4).

Plaintiffs’ only allegation of falsity for these statements is that they “misstated the status of the applications for FDA approval and omitted that [BMS] intended to slow-roll the FDA application process.” *Id.* ¶¶ 162, 165. But as already discussed, there is no contemporaneous factual allegation to support the allegation that BMS intended to “slow-roll” the FDA application process, and the complaint does not plausibly allege that the February 2019 proxy statement “misstated the status” of any FDA application. The applications for liso-cel and ide-cel were not even *filed* until months after the merger had been voted upon. *Id.* ¶¶ 91, 96, 132.

In addition, disclosures that several Celgene product candidates, including liso-cel, were “expected to launch” in 2019 and 2020, that BMS estimated the probability of payment under the CVRs to be 45%, and that there was “uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized,” were opinions. Compl. ¶¶ 158, 163-64 (Statements 1 & 4). Statements about “expectations and projections for the future” are “quintessential opinion statements.” *Shreiber v. Synacor*, 832 F. App’x 54, 57 (2d Cir. 2020); *see Sanofi*, 87 F. Supp. 3d at 531 (statement is opinion if it “express[es] expectations for the future rather than presently existing, objective facts”). Plaintiffs have not satisfied the requirements

articulated in *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175 (2015), for asserting claims based on those statements.

Under *Omnicare*, a statement of opinion or belief is not actionable unless “either ‘the speaker did not hold the belief she professed’ or ‘the supporting fact[s] she supplied were untrue.’” *Tongue*, 816 F.3d at 210 (quoting *Omnicare*, 575 U.S. at 186). To avoid dismissal, a complaint challenging opinion statements must include factual allegations supporting an inference that the speaker did not believe the opinions or that they did not “fairly align[]” with information available *at the time*. *Tongue*, 816 F.3d at 212 (quoting *Omnicare*, 575 U.S. at 189). As with all securities claims, truth or falsity must be “assessed in light of the information available at the time [it was] published.” *Scott v. Gen. Motors Co.*, 46 F. Supp. 3d 387, 394 (S.D.N.Y. 2014), *aff’d*, 605 F. App’x 52 (2d Cir. 2015); *see Charter Twp. of Clinton Police & Fire Ret. Sys. v. KKR Fin. Holdings LLC*, 2010 WL 4642554, at \*16-17 (S.D.N.Y. Nov. 17, 2010) (no actionable omission where plaintiffs failed to allege facts “untainted by the clear eyes of hindsight”).

It is not sufficient for plaintiffs to allege, based entirely on events allegedly occurring far in the future, that at the time of the proxy statement BMS already knew it would not use “diligent efforts” to meet the milestones and already “intended to slow-roll the FDA application process.” Compl. ¶ 159; *see In re Shanda Games Ltd. Sec. Litig.*, 2019 WL 11027710, at \*5-6 (S.D.N.Y. Sept. 30, 2019) (statements concerning projections not actionable because complaint did not allege defendant “was aware of undisclosed facts that would undermine the accuracy of the figures”); *Gissin*, 739 F. Supp. 2d at 502 (“pleadings based on fraud by hindsight are not actionable as a matter of law.”); *see also Shields v. Citytrust Bancorp Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994)

(“misguided optimism . . . does not support an inference of fraud”) (pre-PSLRA).<sup>9</sup>

**B. Claims Based on the Proxy Statement “Sound in Fraud” But Are Not Pleaded With Particularity.**

Plaintiffs’ claims based on the joint proxy statement / prospectus also should be dismissed because they “sound in fraud” and do not meet the heightened pleading requirements of Rule 9(b) and the PSLRA. *Rombach*, 355 F.3d at 171.<sup>10</sup> The allegations that BMS never intended to use “diligent efforts” and intentionally “slow-rolled the FDA application process” to “avoid making the \$6.4 billion CVR payment,” Compl. ¶¶ 159, 162, 167, are the types of accusation “classically associated with fraud[.]” *Rombach*, 355 F.3d at 171. The complaint’s perfunctory disclaimer of any fraud allegation in support of these claims, Compl. ¶¶ 248, 262, 272, 283, does not shield the complaint “from the requirements of Rule 9(b).” *In re JP Morgan Chase*, 363 F. Supp. 2d at 635; *see Rombach*, 355 F.3d at 172.

No allegations exist to support a cogent and compelling inference that BMS or any other defendant made the challenged proxy statement disclosures with an intent to defraud. As already discussed, the complaint offers no allegations of contemporaneous fact to support the conclusory

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<sup>9</sup> The complaint also discusses statements made in a report by Guggenheim Partners. Compl. ¶ 166 (Statement 5); Exh. 2. But an analyst report is not a “registration statement” or a “prospectus,” *see* 15 U.S.C. §§ 77b(a)(8), (10), and the statements are not actionable under the Securities Act, *see* 15 U.S.C. §§ 77k(a), 77l(a)(2). Further, none of the defendants was the “maker” of the report, *Janus Cap. Grp. Inc. v. First Deriv. Traders*, 564 U.S. 135, 142 (2011), nor have plaintiffs met their burden to allege a claim based on the report under pre-*Janus* decisions. *See Zagami v. Cellceutix Corp.*, 2016 WL 3199531, at \*7 (S.D.N.Y. June 8, 2016) (discussing *Novak v. Kasaks*, 216 F.3d 300 (2d Cir. 2000)). A reported statement by Dr. Hirawat on December 8, 2019 (Statement 6, Compl. ¶ 169) is subject to dismissal for the same reason.

<sup>10</sup> *See In re JP Morgan Chase Sec. Litig.*, 363 F. Supp. 2d 595, 635 (S.D.N.Y. 2005) (requiring allegations supporting “strong inference” of scienter for Securities Act claims that sounded in fraud); *see also Caiafa v. Sea Containers Ltd.*, 2008 WL 11516813, at \*5 (S.D.N.Y. May 15, 2008) (dismissing Securities Act claim where plaintiffs failed to “plead with particularity a strong inference of scienter”), *aff’d*, 331 F. App’x 14 (2d Cir. 2009); *In re Marsh & McLennan Cos. Sec. Litig.*, 501 F. Supp. 2d 452, 492 (S.D.N.Y. 2006) (same).

allegation that BMS never intended to use “diligent efforts” and always planned to “slow-roll” the FDA application process. That also amounts to a failure to plead fraud with particularity. *See Ret. Bd. of Policemen’s Annuity & Benefit Fund v. FXCM Inc.*, 333 F. Supp. 3d 338, 351 (S.D.N.Y. 2018) (rejecting claims that sought inference of fraud “merely in hindsight”).

**C. Plaintiffs Have Not Plausibly Alleged Loss Causation for the § 14(a) Claims.**

Plaintiffs’ section 14(a) claims should be dismissed for the additional reason that the complaint does not plausibly allege loss causation. 15 U.S.C. § 78u-4(b)(4); *see Gray*, 454 F. Supp. 3d at 403. Plaintiffs’ allegations do not support a reasonable inference that their alleged loss “was caused by the materialization” of an allegedly concealed risk. *Amorosa v. Ernst & Young*, 672 F. Supp. 2d 493, 504 (S.D.N.Y. 2009) (quoting *Lentell v. Merrill, Lynch & Co.*, 396 F.3d 161, 173 (2d Cir. 2005)); *see* Compl. ¶ 222, 253, 254.

Even while acknowledging that pandemic travel restrictions prevented the FDA from completing the facility inspections needed to approve the liso-cel application until three weeks before the liso-cel milestone date, *see id.* ¶¶ 32, 98, 202, the complaint speculates that CVR holders would have received payment in full – pandemic notwithstanding – if only BMS had not allegedly taken steps “to delay the process.” *Id.* ¶ 230. There never will be a way to test that speculation – it is impossible to conjure an alternative reality in which the pandemic never occurred. Nor are those events connected to an alleged misstatement in the proxy statement disseminated years before. “To permit [plaintiffs] to recover damages on the assumption that” the outcome would have been different if there had been different disclosures in the proxy statement “would give [plaintiffs] a windfall wholly unrelated” to any alleged violation of section 14(a). *Gray*, 454 F. Supp. 3d at 404 (citing *Barrows v. Forest Labs., Inc.*, 742 F.2d 54, 60 (2d Cir. 1984)).<sup>11</sup>

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<sup>11</sup> Lead plaintiff does not allege it acquired CVRs in the Celgene merger and therefore lacks standing to pursue the claims under § 12(a)(2) of the Securities Act § 14(a) of the Exchange Act.

## **II. PLAINTIFFS HAVE NOT ALLEGED AN ACTIONABLE SECURITIES FRAUD CLAIM.**

Upon the closing of the merger with Celgene on November 20, 2019, the CVR Agreement became effective and the CVRs began to trade. Plaintiffs assert that BMS and three of its senior officers – Dr. Caforio, its chief executive officer, Dr. Hirawat, its chief medical officer, and Mr. Elkins, its chief financial officer – committed securities fraud in statements concerning the FDA applications for liso-cel or ide-cel contained in filings, press releases, or presentations between December 8, 2019 and December 31, 2020. *See* Compl. ¶¶ 168-207, 243-47 (Statements 5-24). Plaintiffs allege the statements were false primarily because BMS allegedly intended to cause the FDA to miss at least one milestone to “avoid making the \$6.4 billion CVR payment[.]” Compl. ¶¶ 170, 172, 174, 177, 180, 184, 187, 189, 190, 192, 196, 199, 203, 206. These claims should be dismissed for several different reasons.

### **A. Plaintiffs Have Not Alleged Any Material Misrepresentation.**

#### **1. The Challenged Statements Were Accurate.**

Plaintiffs do not plausibly allege that updates provided on the liso-cel and ide-cel applications and the related FDA approval process reported inaccurate information or expressed opinions that differed in any material respect from the speakers’ honestly held views at the time. Compl. ¶¶ 169, 171, 173-76, 179, 181, 185, 188, 190-91, 193, 195, 197-98, 203 (Statements 6-11, 13-23); *see* 15 U.S.C § 78u-4(b)(1) (requiring plaintiff to specify statement and the reasons it was false).

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*See, e.g., DCML LLC v. Danka Business Sys. PLC*, 2008 WL 5069528, at \*2 (S.D.N.Y. Nov. 26, 2008) (“only shareholders who were entitled to vote on a transaction have standing under section 14(a)”); *In re Cosi, Inc. Sec. Litig.*, 379 F. Supp. 2d 580, 588-89 (S.D.N.Y. 2005) (no § 12(a)(2) standing where plaintiffs did not allege they purchased shares in the offering). Defendants reserve all rights based on the lead plaintiff’s lack of standing if the claims proceed beyond this motion to dismiss.

There is no allegation, for example, that BMS did *not* complete its liso-cel BLA on December 18, 2019, Compl. ¶ 171 (Statement 7); that BMS did *not* “continue to advance [its] regulatory filings,” *id.* ¶ 173 (Statement 8), that the FDA’s “major amendment” letter had *not* extended the liso-cel PDUFA date, *id.* ¶ 179 (Statement 10); that the FDA had *not* asked “specific questions” about the liso-cel application, *id.* ¶ 185 (Statement 13); that the extended PDUFA date for liso-cel was *not* November 16, 2020, *id.* ¶¶ 179, 181, 185, 188, 190, 191, 193 (Statements 10, 11, 13-17); that there was *no possibility* the COVID-19 pandemic could “delay the timing of the FDA’s approval decisions” or its inspection of liso-cel manufacturing facilities, *id.* ¶¶ 179, 188, 191, 195, 198 (Statements 10, 14, 16, 18, 20); or that BMS was *not* “working very actively” or “closely” with the FDA or that its communications with the agency were *not* “going well,” *id.* ¶¶ 191, 195, 201, 202, 205 (Statements 16, 18, 22-24).

More generally, as already discussed, there are no plausible factual allegations to support plaintiffs’ oft-repeated assertion that challenged statements were misleading because BMS intended to “slow-roll the FDA application process” in order to “avoid making the \$6.4 billion CVR payment.” *E.g., id.* ¶ 170; *see supra* at 16-21. The complaint also fails to provide any contemporaneous factual allegation to support plaintiffs’ contention that “BMS knew,” but failed to disclose, that its applications for FDA approval of liso-cel and ide-cel were “deficient,” “insufficient,” or “deliberately or recklessly incomplete.” *See* Compl. ¶¶ 170, 172, 174, 177, 182, 184, 187, 189, 190, 192, 194, 196, 199.

For both of these contentions, allegations about future setbacks in the FDA approval process are not sufficient: the securities laws did not require BMS or the individual defendants to predict the future. *See Gallagher v. Abbott Labs.*, 269 F.3d 806, 810 (7th Cir. 2001) (“Unless Abbott had a time machine, it could not have described on March 9 a letter that had yet to be

written.”). Instead, truth or falsity must be “assessed in light of the information available at the time,” *Scott*, 46 F. Supp. 3d at 394; *KKR Fin. Holdings*, 2010 WL 4642554, at \*16-17, and the complaint does not allege any contemporaneous fact that would support these allegations of falsity.<sup>12</sup>

Similarly, the complaint does not plausibly allege that any statement was false or misleading based on the conclusory assertion that BMS was “deliberately or recklessly not preparing adequately for inspections of its two [l]iso-cel manufacturing facilities.” Compl. ¶¶ 180, 182, 184, 187, 189, 190, 192, 194, 196, 199.<sup>13</sup> For this assertion, plaintiffs rely primarily on FDA comments issued *after* the inspections. *See id.* ¶¶ 107-11, 116-24. Once again, however, that is impermissible hindsight pleading. *See Shields*, 25 F.3d at 1129; *Gissin*, 739 F. Supp. 2d at 502. After-the-fact observations from the FDA do not support a plausible inference that BMS knew, months earlier, that the same issues would be raised when the inspections eventually took place. *See* Compl. ¶¶ 113, 116. Moreover, BMS addressed the FDA’s inspection comments *before* the liso-cel milestone date, *id.* ¶¶ 113, 114, 126, and the FDA approved the application soon thereafter, *id.* ¶ 127, casting significant doubt on plaintiffs’ contention that the FDA’s comments raised significant issues about the facilities’ readiness.

Allegations from alleged “confidential witnesses” who worked for Lonza, not for BMS, also do not support a plausible inference that BMS or the other defendants were aware of any material issues at the time of any challenged statement. *Id.* ¶¶ 120, 121, 123; *see Campo v. Sears*

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<sup>12</sup> As already discussed, the hindsight opinions of plaintiffs’ unidentified “FDA Biologics Expert” are not contemporaneous, contrary facts and are not entitled to “a presumption of truthfulness.” *NYSE Specialists Sec. Litig.*, 503 F.3d at 95; *see Chipotle Mexican Grill Inc.*, 294 F. Supp. 3d at 223-24 (refusing to consider opinions of food safety expert).

<sup>13</sup> The focus of these allegations is a facility owned and operated by Lonza, and not by BMS, and for that location, plaintiffs allege, BMS’s role was limited to “monitoring and instructing its contract vendor.” *Id.* ¶ 103.

*Holding Corp.*, 371 F. App'x 212, 217 (2d Cir. 2010) (dismissing claims where confidential witnesses did not know if defendants “actually accessed or reviewed the reports”); *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 594 (S.D.N.Y. 2011) (rejecting confidential witness allegations where complaint did not allege they “ever had any contact with anyone at [company], much less with the Individual Defendants”). If anything, the “confidential witness” allegations show that BMS was *not* trying to “slow-roll” the FDA approval process, as plaintiffs repeatedly allege. *See* Compl. ¶ 120 (alleging BMS conducted mock audit, organized task force, held regular calls with Lonza, and even “berated and screamed at CW #2” when things “were not going well”).

Regardless, there was no duty to discuss BMS’s readiness for the facility inspections or other details of its interactions with the FDA at the time of any of the challenged statements. *See Sanofi*, 87 F. Supp. 3d at 541-42 (no duty even to discuss *results* of FDA inspections) (collecting cases); *see, e.g., Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 52 (2d Cir. 1995) (rejecting claim based on alleged failure to disclose preliminary inspection results where “no materially adverse action was taken by the FDA,” and company “had made commitments to the FDA to correct the plant deficiencies”).

Even if the defendants had known about purported issues before the inspections – which the complaint does not plausibly allege – “[d]isclosure is not a rite of confession,” and companies do not have a duty “to disclose uncharged, unadjudicated wrongdoing.” *City of Pontiac Policemen’s & Firemen’s Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) (quoting *Morgan Stanley Info. Fund*, 592 F.3d at 365); *see, e.g., In re Citigroup, Inc. Sec. Litig.*, 330 F. Supp. 2d 367, 377 (S.D.N.Y. 2004) (rejecting claim based on “failure to disclose that its revenues were derived from ‘unsustainable and illegitimate sources’”).

Nor did BMS subject itself to any duty to discuss the facilities' *preparedness* for inspections when it commented on pandemic-related challenges in *scheduling* them. *FindWhat Inv'r Grp. v. FindWhat.com*, 658 F.3d 1282, 1305 (11th Cir. 2011) ("Requiring that disclosures be "complete and accurate" . . . does not mean that by revealing one fact about a product, one must reveal all others that, too, would be interesting, market-wise.") (quoting *Backman v. Polaroid Corp.*, 910 F.2d 10, 16 (1st Cir. 1990)).

## **2. The Safe Harbor Bars Liability for Most of the Challenged Statements.**

In addition, most of the challenged statements alleged in plaintiffs' securities fraud claims were forward-looking, and the defendants are protected from liability for those statements by the PSLRA safe harbor. 15 U.S.C. § 78u-5(c)(1); *see also* 15 U.S.C. § 78u-5(c)(2) (oral statements). The forward-looking statements included: predictions about BMS's ability to meet the CVR milestones, Compl. ¶¶ 176, 205 (Statements 9, 24); the possibility of delays in the FDA approval process, *id.* ¶¶ 179, 188, 191, 195, 198 (Statements 10, 14, 16, 18, 20); and the potential timing for filings or regulatory approval, *id.* ¶¶ 169, 183, 185, 190, 202 (Statements 6, 12, 13, 15, 23). These statements concerning an ongoing or future FDA approval process were "classically forward-looking[.]" *Sanofi*, 87 F. Supp. 3d at 535; *Gillis*, 197 F. Supp. 3d at 585; *see* 15 U.S.C. §§ 78u-5(i)(1)(A), (B), (D).

Plaintiffs have not alleged facts that would support an inference that any of the defendants had "actual knowledge" of the falsity of any of these statements at the time they were made, for the reasons discussed above. *See supra* at 16-21; 15 U.S.C. §§ 78u 5(c)(1). The statements also were accompanied by meaningful cautionary language. BMS provided CVR-specific risk factors in its Form 10-K, filed on February 24, 2020, and in its Forms 10-Q filed on May 7, August 6, and November 5, 2020. *See* Clarke Decl. Exhs. 4, 9, 12 & 14. In the Form 10-K, BMS identified as forward-looking any statement concerning, "among other things, . . . product development,

product approvals, . . . [and] our ability to realize the projected benefits of the acquisition of Celgene[.]” Exh. 4 at 56. The risk factors warned that “if the milestones specified in the CVR agreement are not achieved *for any reason* within the time periods specified therein, no payment will be made under the CVRs and the CVRs will expire without value.” *Id.* at 27 (emphasis added).<sup>14</sup>

These warnings were reiterated in the Forms 10-Q filed during the balance of 2020. *See* Exh. 9 at 44; Exh. 12 at 51; Exh. 14 at 54. In addition, the Forms 10-Q warned “that the COVID-19 pandemic could delay the timing of the FDA’s approval decisions” and, if FDA review extended past the milestone dates, “no payment will be made under the CVRs and the CVRs will expire without value.” Exh. 9, at 46; Exh. 12 at 53; Exh. 14 at 56. BMS referred investors to these cautionary statements in each of the press releases and earnings calls plaintiffs challenge. *See* Exhs. 5-8, 10-11, 13, 15-16. The cautionary statements meaningfully warned investors about the risk that the CVRs might expire valueless if the FDA did not, for any reason, approve any of the three applications by its milestone date. This protects the speakers from liability. *See Sanofi*, 87 F. Supp. 3d at 536; *see Delcath*, 36 F. Supp. 3d at 334.

### **3. Some Challenged Statements Were Inactionable Puffery or Opinions.**

Some of the challenged statements include assertions that BMS was “committed” to working with the FDA or obtaining FDA approval of liso-cel, that it would “continue to work closely” with the FDA, that it was “looking forward” to obtaining FDA approval, and that the regulatory process was “going well.” Compl. ¶¶ 176, 181, 190-91, 195, 202, 205 (Statements 9, 11, 15, 16, 18, 23, 24). Such indefinite expressions of corporate optimism and aspiration are not

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<sup>14</sup> The Court may examine the alleged misrepresentations and any accompanying cautionary statement in deciding this motion. 15 U.S.C. § 78u-5(e).

actionable. *Abramson v. Newlink Genetics Corp.*, 965 F.3d 165, 174 (2d Cir. 2020); *UBS AG*, 752 F.3d at 183. Alternatively, those statements were opinions as to which plaintiffs have not met their burden under *Omnicare*. *See supra* at 18-20.

**B. Plaintiffs Have Not Alleged Facts That Give Rise to the Required “Strong Inference” of Scierter.**

The securities fraud claims also should be dismissed because plaintiffs have failed to “state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind.” *JP Morgan Chase Co.*, 553 F.3d at 196 (quoting 15 U.S.C. § 78u-4(b)(1)-(2)). To constitute the required “strong inference,” the inference of scierter drawn from a complaint’s allegations “must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs*, 551 U.S. at 314.

In the Second Circuit, a plaintiff can plead scierter in two ways: “(a) by alleging facts to show that defendants had both the motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.” *Kalnit v. Eichler*, 264 F.3d 131, 138 (2d Cir. 2001). Pleading “motive and opportunity” requires plausible allegations that a defendant “benefitted in some concrete and personal way from the purported fraud.” *JP Morgan Chase Co.*, 553 F.3d at 198. Where (as here) no such showing is made, “the strength of the circumstantial allegations” of the defendants’ fraudulent intent in making the challenged statements “must be correspondingly greater.” *Id.* at 198-99.

**1. Plaintiffs’ Motive Allegations Are Implausible.**

There are no allegations that any of the defendants engaged in transactions in BMS securities during the putative class period. “The absence of stock sales by insiders, or any other evidence of pecuniary gain by company insiders at shareholders’ expense, is inconsistent with an intent to defraud[.]” *In re N. Telecom Ltd. Sec. Litig.*, 116 F. Supp. 2d 446, 462 (S.D.N.Y. 2000).

Instead, plaintiffs’ principal motive allegation is that BMS intentionally “slow-roll[ed]” the FDA approval process for liso-cel “for the purpose of avoiding a \$6.4 billion payment to CVR holders.” Compl. ¶ 1; *see id.* ¶ 221. This allegation, repeated throughout the complaint, “defies economic reason” and cannot support even a “reasonable inference” of scienter, much less the required “strong” inference. *JP Morgan Chase Co.*, 553 F.3d at 203.

Plaintiffs allege that BMS was required by contract to use “diligent efforts” to obtain FDA approval of liso-cel and two other product candidates by the milestone dates in the CVR Agreement. Compl. ¶ 16; *see id.* ¶ 88 (quoting contract provision). But any deliberate effort by BMS to prevent timely FDA approval – the essence of all of plaintiffs’ claims here – undoubtedly would have exposed BMS to potential liability for breach of the same provision. It therefore would not have “spare[d] [BMS] a \$6.4 billion payout,” as plaintiffs allege. *Id.* ¶ 6.

Given the risk of a breach of contract claim arising from the deliberate actions plaintiffs allege, any benefit BMS might have obtained by intentionally disregarding its “diligent efforts” obligations would have been illusory. That alone renders implausible plaintiffs’ primary motive allegation. *See In re AT&T/DirectTV Now Sec. Litig.*, 480 F. Supp. 3d 507, 533 n.26 (S.D.N.Y. 2020) (allegation that defendant “knew from the beginning” that product would not be profitable was implausible because it would make “no economic sense for AT&T to have acquired Time Warner for over \$100 billion, to have fought off a DOJ antitrust challenge to the merger,” and to make significant investments thereafter “if it did not genuinely believe that [it] would be a successful and profitable product”).

Moreover, corporations do not have minds of their own. To plead corporate scienter, “the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter.” *Francisco v. Abengoa, S.A.*, 481 F. Supp. 3d 179,

214 (S.D.N.Y. 2020) (quoting *Teamsters Local 445 Freight Div. Pension Fund v. Dynex Capital Inc.*, 531 F.3d 190, 195 (2d Cir. 2008)). But as already noted, there are no allegations that any individual defendant engaged in transactions in BMS securities during the alleged class period. Indeed, many former Celgene officers and employees who continued in their roles for the FDA approval process were holders of CVRs that they received in the merger for their Celgene equity. See Clarke Decl. Exh. 4 at 110 (Form 10-K).

Plaintiffs’ convoluted assertion that the three individual defendants were incentivized to commit fraud because the Compensation Committee later granted them long-term incentive compensation, Compl. ¶¶ 143-49, is not the kind of “concrete and personal benefit” required to plead motive and opportunity. *Kalnit*, 264 F.3d at 139; see *Novak v. Kasaks*, 216 F.3d 300, 307 (2d Cir. 2000) (opportunity “entail[s] the means and likely prospect of achieving concrete benefits by the means alleged”). Plaintiffs’ additional allegation that the individual defendants *indirectly* benefitted through the increased value of BMS stock, *id.* ¶ 151, is a motive “generally possessed by most corporate directors and officers” that also is not sufficient. *Kalnit*, 264 F.3d at 139; see *Total Equity Cap., LLC v. Flurry, Inc.*, 2016 WL 3093993, at \*5 (S.D.N.Y. June 1, 2016) (Furman, J.). Moreover, the complaint does not allege that the price of BMS stock actually increased. See Compl. ¶ 150 (citing securities analyst estimate of increased BMS equity value, not stock price).

Finally, this is not one of the “exceedingly rare instances” where an alleged statement is “so dramatic” that collective corporate scienter can be inferred. *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020). Allegations of typical corporate motives, such as an incentive to prevent a drop in its “credit rating or stock price,” are “far too generalized (and generalizable)” to meet this narrow exception. *In re PXRE Grp., Ltd., Sec. Litig.*, 600 F. Supp. 2d 510, 532 (S.D.N.Y. 2009) (Sullivan, J.), *aff’d*, 357 F. App’x 393 (2d Cir. 2009). The complaint does not include any such

“dramatic” misrepresentation. To the contrary, it shows a pattern of keeping investors apprised of developments in the FDA approval process and prompt disclosure when FDA approval for liso-cel was not obtained by the milestone date. This conduct is the opposite of fraudulent.<sup>15</sup>

**2. The Complaint Does Not Plead Conscious Misbehavior or Recklessness.**

Given plaintiffs’ failure to establish a “strong inference” of scienter through their motive and opportunity allegations, plaintiffs were required to plead “strong circumstantial evidence” that the challenged statements were intentionally fraudulent or, at least, made with “recklessness.” *Marcu v. Cheetah Mobile Inc.*, 2020 WL 4016645, at \*7 (S.D.N.Y. July 16, 2020) (Furman, J.). “Plaintiffs’ allegations here fall short of these demanding requirements.” *Id.*

Plaintiffs’ circumstantial case relies heavily on allegations that setbacks in the FDA approval process for liso-cel were “rare,” “unusual,” or “contrary to standard industry practice.” Compl. ¶ 211-17. Plaintiffs ignore, however, that BMS obtained FDA approval for *all three* of the relevant product applications largely within the timeframes agreed to at the time of the merger agreement two years earlier – and despite the acknowledged impact on the FDA’s operations arising from the worst pandemic in 100 years. *See id.* ¶¶ 95, 135, 216.

The well-understood impact of the COVID-19 pandemic on the FDA’s operations – including specifically its ability to conduct inspections – defeats an inference of scienter based on a “comparison of the [l]iso-cel approval timeline to other biologics[.]” Compl. ¶ 217; *see id.* ¶ 202

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<sup>15</sup> Similarly implausible is plaintiffs’ allegation that BMS chose not to buy back CVRs when they were trading at low values because it did not want to reveal its “ulterior undisclosed motive.” Compl. ¶ 94. The explanation BMS allegedly provided at the time is far more plausible: that it had no plans to buy back CVRs because of the asymmetry of information between BMS and CVR investors. *Id.* ¶ 92. No court has ever determined that “a corporation’s failure to purchase [its securities] during the class period[] is sufficient to establish motive.” *Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 337-38 (S.D.N.Y. 2011).

(“As you know, [the FDA] are doing what they can to ensure that the staffs are kept safe in this COVID pandemic. And because of the travel restrictions, we have to obviously honor their desire to where they go and when they go.”). More generally, it is implausible on its face for plaintiffs to allege that BMS exercised control over an opaque regulatory approval process and did so with such finesse that the FDA approved liso-cel, to BMS’s alleged benefit, only after the milestone date elapsed five weeks later. Compl. ¶¶ 130, 135.

Moreover, plaintiffs’ allegations of flawed applications or unprepared manufacturing facilities are thinly veiled allegations of “at most, corporate mismanagement” that do not amount to “actionable securities fraud.” *In re Lululemon Sec. Litig.*, 14 F. Supp. 3d 553, 562 (S.D.N.Y. 2014) (citing *Santa Fe Indus., Inc. v. Green*, 430 U.S. 462, 477-79 (1977)); *see Fries v. N. Oil & Gas, Inc.*, 285 F. Supp. 3d 706, 721 (S.D.N.Y. 2018) (“[C]orporate mismanagement does not constitute recklessness.”).

Plaintiffs’ “confidential witness” allegations also do not support an inference of scienter. If anything, they *undermine* such an inference. The only “confidential witness” ever allegedly employed by BMS or Celgene – CW #1 – was not alleged to have had any contact with BMS senior officers and offered no allegations in conflict with the challenged public statements. The allegation that CW #1 was “deeply disappointed” by the FDA’s “major amendment” letter, rather than being unsurprised, directly conflicts with plaintiffs’ theory of intentional delay. Compl. ¶ 101.

All of the other “confidential witnesses” allegedly worked for Lonza, not for BMS. As already discussed, allegations attributed to CW #2 and CW #3 support the inference that BMS was working diligently to obtain FDA approval for liso-cel by the milestone date. *Id.* ¶ 120; *see supra* at 25-26. Others allegedly identified various issues at the Lonza facility, but there is no plausible

allegation that BMS disregarded those issues even if it is assumed they knew about them. *Id.* ¶¶ 121, 123. There is no allegation that *any* of the defendants was aware of the alleged operational issues at the Lonza facility. That deficiency alone defeats any inference of scienter. *See Campo*, 371 F. App'x at 217; *Glaser*, 772 F. Supp. 2d at 594.

### **C. Plaintiffs Have Not Plausibly Alleged Loss Causation.**

The securities fraud claims also should be dismissed because plaintiffs have not plausibly alleged loss causation, that is, a “causal link between the alleged misconduct and the economic harm ultimately suffered by the plaintiff.” *Lentell*, 396 F.3d at 172; *see* 15 U.S.C. § 78u-4(b)(4) (loss causation is plaintiffs’ burden). Meeting that burden requires plausible allegations of a “corrective disclosure.” *Born v. Quad/Graphics, Inc.*, 521 F. Supp. 3d 469, 494 (S.D.N.Y. 2021). Where such a disclosure “contain[s] no information that even remotely suggests that [d]efendants’ prior statements . . . were false or misleading[,]” dismissal is required. *Id.* (citing *Lentell*, 396 F.3d at 175 n.4).

None of the alleged “corrective disclosures” alleged in the case here revealed a “fraud” that had been concealed by a previous misrepresentation. While the price of CVRs allegedly declined after disclosures on May 6, September 8, November 5, and November 16, 2020, Compl. ¶¶ 225-28, there are no facts alleged that would permit an inference that the price declines were in response to the revelation of fraud. Instead, the plausible inference is that the price responded to an increased risk that a CVR milestone would be missed resulting in no payment, which was precisely the risk BMS repeatedly warned could materialize. *Id.* ¶¶ 179, 188, 198.

“There is no allegation that the market reacted negatively to a corrective disclosure *regarding the falsity*” of any prior statement, “and no allegation that [BMS] misstated or omitted risks that did lead to the loss.” *Lentell*, 396 F.3d at 175 (emphasis added); *see Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 232-33 (2d Cir. 2014) (loss causation

adequately pleaded where corrective disclosure of alleged misrepresentations tied directly to significant stock price decline). Plaintiffs “are reduced to relying on” accurate disclosures concerning developments in the FDA approval process “and concomitant market dissatisfaction to allege loss causation. That is simply not enough.” *Born*, 521 F. Supp. 3d at 494.

**III. THE “CONTROLLING PERSON” CLAIMS ALSO SHOULD BE DISMISSED.**

Because plaintiffs have not alleged a primary violation of either the Securities Act or the Exchange Act, and also given plaintiffs’ failure to allege that any of the individual defendants named in their securities fraud claims was a “culpable participant” in any fraud, the “controlling person” claims under Securities Act § 15 and Exchange Act § 20(a) also should be dismissed. *JP Morgan Chase Co.*, 553 F.3d at 206-07; *ATSI*, 493 F.3d at 108.

**CONCLUSION**

For the foregoing reasons, the complaint should be dismissed in its entirety.

Dated: New York, New York  
April 8, 2022

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**APPENDIX 1**

*In re Bristol-Myers Squibb Co. CVR Securities Litigation*, Case No. 1:21-cv-08255 (JMF)  
Chart of Allegedly False or Misleading Statements<sup>1</sup>

<u>Statement No.</u>	<u>Compl. Paragraph(s)</u>	<u>Date</u>	<u>Source and Alleged Speaker(s)</u>	<u>Text of Challenged Statement</u>	<u>Summary of Reasons Not Actionable</u> (See Memorandum of Law)
1	¶ 158	2/22/19	Source: Merger Proxy Statement  Alleged Speakers: BMS Peter J. Arduini Robert Bertolini Giovanni Caforio Matthew W. Emmens Michael Grobstein Alan J. Lacy Dinesh C. Paliwal Theodore R. Samuels Vicki L Sato Gerald L. Storch Karen H. Vousden	<i>“Celgene’s key late-stage product candidates, which are expected to launch in 2019 and 2020, are ozanimod, fedratinib, luspatercept, [Liso-cell], and [Ide-cell].”</i>  <i>“Bristol-Myers Squibb management provided an estimate of the probability of achieving the three FDA approvals required to trigger the \$9 payment under the CVR agreement to the BMS Board in connection with its evaluation of the merger, and to each of Morgan Stanley, Dyal Co. and Evercore for purposes of their respective financial analyses and opinions. This estimate [] was 45%.”</i>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 77z-2</li> <li>• Non-actionable statement of opinion under <i>Omnicare</i></li> </ul>
2	¶ 160	2/22/19	Source: Merger Proxy Statement  Alleged Speakers: BMS Peter J. Arduini Robert Bertolini Giovanni Caforio Matthew W. Emmens Michael Grobstein Alan J. Lacy Dinesh C. Paliwal Theodore R. Samuels	<i>“The CVRs are contingent value rights to be issued by Bristol-Myers Squibb as part of the merger consideration to Celgene stockholders and certain holders of Celgene equity awards. Each CVR represents the right to receive a one-time cash payment of \$9.00 if the [] FDA, approves, by the [Milestones].”</i>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 77z-2</li> <li>• Non-actionable statement of opinion under <i>Omnicare</i></li> </ul>

<sup>1</sup> All emphases are as they appear in the complaint.

<u>Statement No.</u>	<u>Compl. Paragraph(s)</u>	<u>Date</u>	<u>Source and Alleged Speaker(s)</u>	<u>Text of Challenged Statement</u>	<u>Summary of Reasons Not Actionable</u> (See Memorandum of Law)
			Vicki L Sato Gerald L. Storch Karen H. Vousden		
3	¶ 161	2/22/19	Source: Merger Proxy Statement  Alleged Speakers: BMS Peter J. Arduini Robert Bertolini Giovanni Caforio Matthew W. Emmens Michael Grobstein Alan J. Lacy Dinesh C. Paliwal Theodore R. Samuels Vicki L Sato Gerald L. Storch Karen H. Vousden	“Bristol-Myers Squibb has agreed to use ‘diligent efforts’ to achieve the CVR milestone. ‘Diligent efforts’ means, with respect to [Ide-cel], [Liso-cel] or Ozanimod, efforts of a person or entity to carry out its obligations in a diligent manner using such effort and employing such resources <b><i>normally used by such person or entity in the exercise of its reasonable business discretion relating to the research, development or commercialization of a product</i></b> , that is of similar market potential at a similar stage in its development or product life, taking into account issues of market exclusivity (including patent coverage, regulatory and other exclusivity), safety and efficacy, product profile (including tolerability and convenience), the competitiveness of alternate products in the marketplace or under development, the launch or sales of one or more generic or biosimilar products, actual or likely pricing/reimbursement [Ide-cel], [Liso-cel] or Ozanimod [sic], the likely timing of such product’s entry into the market, the likelihood of regulatory approval of such product and applicable labeling, and the profitability of such product, and other relevant factors, including technical, commercial, legal, scientific, and/or medical factors, based on conditions then prevailing.”	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 77z-2</li> <li>• Non-actionable statement of opinion under <i>Omnicare</i></li> </ul>
4	¶¶ 163-64	2/22/19	Source: Merger Proxy Statement	<b><i>“Your right to receive any future payment on the CVRs will be contingent upon the achievement of certain agreed upon U.S. regulatory milestones within the time periods specified in the CVR agreement . . . . Accordingly, the value, if any, of the CVRs is speculative, and the CVRs may ultimately have no value.”</i></b> Compl. ¶ 163.	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 77z-2</li> <li>• Non-actionable statement of opinion under <i>Omnicare</i></li> </ul>

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			Alleged Speakers: BMS Peter J. Arduini Robert Bertolini Giovanni Caforio Matthew W. Emmens Michael Grobstein Alan J. Lacy Dinesh C. Paliwal Theodore R. Samuels Vicki L Sato Gerald L. Storch Karen H. Vousden	“There is also uncertainty regarding the fair market value of the CVRs and whether any payment will ultimately be realized on the CVRs. Accordingly, at the time of the Celgene special meeting, Celgene stockholders will not know or be able to determine the market value of the merger consideration they would be entitled to receive upon completion of the merger.” Compl. ¶ 164.	
5	¶ 166	11/7/19	Source: Guggenheim Partners Analyst Report  Alleged Speaker: Guggenheim Partners	“ <b>Management emphasized several points, including (1) oversight of the CVR is a board-level responsibility and BMY is highly motivated to pay out the CVR because of the importance of the CELG pipeline to the company’s future value;</b> but (2) BMY has no plans to buy back the CVR early, either via open market purchases or a tender primarily because of the availability of asymmetric information available to BMY vs. the shareholders of the CELG CVR. As it relates to the CVR, we expect shares to trade purely on the events and probability that all three events are achieved in the allotted timeline.”	<ul style="list-style-type: none"> <li>Analyst report is not a “registration statement” or a “prospectus,” 15 U.S.C. §§ 77b(a)(8), (10)</li> <li>Statements not attributable to BMS or any individual defendants</li> <li>Statement not adequately alleged to be false or misleading</li> </ul>
6	¶ 169	12/8/19	Source: Presentation at American Society of Hematology  Alleged Speaker: Samit Hirawat	“On December 8, 2019, [Dr. Samit] Hirawat presented at the American Society of Hematology conference. According to a subsequent analyst report, he ‘reiterated plans to file liso-cel for approval by the end of the year, which the report noted ‘should ease concerns on timing for the CVR.’”	<ul style="list-style-type: none"> <li>Statement not adequately alleged to be false or misleading</li> <li>Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>Non-actionable statement of opinion under <i>Omnicare</i></li> <li>Statements not attributable to BMS or any individual defendants</li> <li>No scienter</li> </ul>

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7	¶ 171	12/18/19	Source: Press Release  Alleged Speaker: BMS	<p>“Bristol-Myers Squibb Company (NYSE: BMY) today announced the submission of its Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for lisocabtagene maraleucel (liso-cel), its autologous anti-CD19 chimeric antigen receptor (CAR) T-cell immunotherapy comprising individually formulated CD8+ and CD4+ CAR T cells for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma (LBCL) after at least two prior therapies.</p> <p>The submission is based on the safety and efficacy results from the TRANSCEND NHL 001 trial, evaluating liso-cel in 269 patients with relapsed/refractory large B-cell lymphoma, including diffuse large B-cell lymphoma (DLBCL).”</p>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• No scienter</li> </ul>
8	¶ 173	2/6/20	Source: Earnings Call  Alleged Speaker: Giovanni Caforio	<p>“On February 6, 2020 earnings call, Defendant Caforio stated that ‘we continue to advance our regulatory filings for liso-cel, ide-cel and CC486.’”</p>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• No scienter</li> </ul>
9	¶ 176	5/6/20	Source: Press Release  Alleged Speaker: BMS	<p><b>“The company will work closely with the FDA to support the continued review of the BLA for liso-cel and is committed to bringing this therapy to patients.</b></p> <p style="text-align: center;">***</p> <p><b>The company is committed to working with FDA to progress both applications and achieve the remaining regulatory milestones required by the CVR.”</b></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>

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10	¶ 179	5/7/20	Source: Form 10-Q  Alleged Speakers: BMS Giovanni Caforio David Elkins	<p><b>“Announced that the FDA has extended the PDUFA date by three months for the BLA for lisocabtagene maraleucel (liso-cel), a CD19-directed CAR T cell therapy for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date set by the FDA is November 16, 2020. . . .</b></p> <p><b>It is possible that the COVID-19 pandemic could delay the timing of the FDA’s approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).</b></p> <p>We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). <b>These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020. . . . It is possible that COVID-19 could impact FDA operations such that the review of either or both of these CVR assets could be delayed.</b> Any delay in the timing of approval could reduce the resale price of the CVR. If there is a significant delay that extends the FDA’s review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.”</p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• No scienter</li> </ul>

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11	¶ 181	5/7/20	Source: Earnings Call  Alleged Speaker: Samit Hirawat	<p><b>“FDA has decided that the information they have received constitute a major amendment, and that’s why the PDUFA date has been extended by 3 months to 16th of November now. And we are obviously committed to ensuring this medicine is available to patients as soon as possible, and we continue to meet our CVR milestones.</b> Obviously we’re not going to comment on the specifics of our regulatory discussions, but let me just remind that we remain very confident about the data for liso-cel for these patients with large B-cell lymphoma as it is an unmet medical need, and <i>we are truly looking forward to get approval of this therapy towards the end of the year.</i> Thank you. . . .</p> <p><b>It is very normal for the FDA to, as they review the file, to ask questions. Certainly, we are looking towards the approval date now to end November. . . .</b></p> <p><i>We remain confident and we are looking forward to bringing this treatment to patients as soon as possible towards the end of this year.”</i></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>
12	¶ 183	5/19/20	Source: Presentation at UBS Virtual Global Healthcare Conference  Alleged Speaker: Samit Hirawat	<p>“On May 19, 2020, during a presentation at the UBS Virtual Global Healthcare Conference, Defendant Hirawat stated that <i>‘we look towards hopefully approval of liso-cel towards the end of this year and we continue to go forward.’</i>”</p>	<ul style="list-style-type: none"> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Non-actionable puffery or statement of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>

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13	¶ 185	6/25/20	Source: Presentation at BMS Investor Day Series  Alleged Speaker: Samit Hirawat	<p>“Liso-cel has a best-in-class CD19 targeting profile with the high affinity and differentiated safety. <b>We look forward to bring this call [sic] to patients soon because we have a PDUFA date of November 16 this year. . . .</b></p> <p><b>So what we learned, as we said on the call, around the [ide-cel] refusal to file, there were a lot many more questions around the data required in the filing from a CMC perspective. . . . For liso-cel, there are specific questions that were asked that required for us to provide more data that were considered to be large enough that the agency needed to do the scientific review of it and extended the time line through a major amendment. . . .”</b></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>
14	¶ 186	6/25/20	Source: Presentation at BMS Investor Day Series  Alleged Speaker: Giovanni Caforio	<p>“Defendant Caforio then reiterated that they felt confident about achieving approval in time for the CVR Milestone, stating that ‘<b>we feel really good about where we are from a regulatory perspective. So that applies to products that may be included in the CVR</b> as well as the rest of the portfolio.’” Compl. ¶ 186.</p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>

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15	¶ 188	8/6/20	Source: Form 10-Q  Alleged Speakers: BMS Giovanni Caforio David Elkins	<p>“Announced that <b>the FDA has extended the action date by three months for the liso-cel BLA for the treatment of adults with relapsed or refractory large B-cell lymphoma after at least two prior therapies. The new PDUFA date is November 16, 2020.</b> . . .</p> <p><b>It is possible that the COVID-19 pandemic could delay the timing of the FDA’s approval decisions for liso-cel and ide-cel, which could have a material adverse effect on our contingent value rights (CVRs).</b></p> <p>We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying our CVRs (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). <b>These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020. . . . It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed.</b> Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA’s review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.”</p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• No scienter</li> </ul>
16	¶ 190	8/6/20	Source Earnings Call  Alleged Speaker: Giovanni Caforio.	<p>“On an August 6, 2020 earnings call, Defendant Caforio stated that ‘in the very near term, <b>we are looking forward to the U.S. PDUFA dates for CC-486 in September and Liso-cel in November.</b> And of course beyond our new launches, we have a pipeline full of promise.’”</p>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Non-actionable puffery or statement of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>

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17	¶ 191	9/8/20	Source: Citibank 15th Annual BioPharma Conference Presentation  Alleged Speaker: Samit Hirawat	<p>“And certainly with the evolution of the COVID-19, as well as the challenges it has posed, both for us and for the FDA, it does pose a risk because the FDA staff, like many of us, are operating under those significant constraints on travel because of COVID. Now with that said, while we typically don't provide any details on regulatory discussions, what I can say today is the FDA has informed us that they will require inspection of both our facilities in Washington State as well as the manufacturing organization for the vector, which is located in Texas. These inspections have not yet taken place. We are working very closely with the FDA to keep this application on track. <b>And as you know, the PDUFA date is in November, we still have some time to go. But at the same time, we are aware that some of the people -- same people who are at the FDA who will be working or working right now on liso-cel, will also be pulled into the inspection related activities that might be coming along for the COVID-related vaccines.</b> Now FDA is very well aware of that. They are juggling multiple things. As this is a public health crisis and they need to manage, as well as the diseases that are life-threatening, they also need to manage that. So those are all running in parallel. <b>I don't think we can say anything more except that the importance of this application is very, very high for us. I think it is also as important from the FDA perspective. And we will continue to work closely with them, so that we can bring this product to the patients as soon as possible.</b>”</p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>
18	¶ 193	9/15/20	Source: Panel Discussion  Alleged Speaker: Samit Hirawat	<p>“<b>Our PDUFA date, everybody knows, is in November, so we'll just keep on that.</b>”</p>	<ul style="list-style-type: none"> <li>• Statement not adequately alleged to be false or misleading</li> <li>• Forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• No scienter</li> </ul>

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19	¶ 195	9/17/20	Source: Morgan Stanley 18th Annual Global Health Care Conference Presentation  Alleged Speaker: Giovanni Caforio	<b>“I would say the overall process with the FDA is going well. At the same time, as we mentioned last week, the FDA has informed us that they will want to inspect, they will need to inspect both of our work plans during the review process and when we presented last week, those inspections had clearly not yet occurred. So obviously there’s the COVID and the complexity of travel during this time and I would say that is a main concern, somewhat increases the risk to the process. I don’t think there’s much I can add at this point. I can tell you <i>we’re working very actively with the FDA to keep the review and the inspection process moving because we want to get the product to patients as soon as possible</i> and we’ve updated the market last week and there’s nothing I can add at this point.”</b>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>
20	¶ 197	11/5/20	Source: Form 10-Q  Alleged Speakers: BMS Giovanni Caforio David Elkins	<p>“Contingent Value Right Update</p> <p>We have filed BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction that have not been approved by the FDA. The applications are under review by the FDA. . . . Unless the FDA approves liso-cel for the treatment of relapsed-refractory diffuse large B cell lymphoma in humans by December 31, 2020 and ide-cel for the treatment of relapsed/refractory multiple myeloma in human by March 31, 2021, no payment will be made under the CVRs and the CVRs will expire valueless. <b>The FDA has informed us that inspections of two manufacturing facilities are required before they can issue a decision on the liso-cel application. One of those inspections has occurred; the other has not yet been scheduled. We do not believe that the scheduling of the second site inspection is dependent on the outcome of the first site’s inspection, as they are independent facilities.”</b></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• No scienter</li> </ul>

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21	¶ 198	11/5/20	Source: Form 10-Q  Alleged Speakers: BMS Giovanni Caforio David Elkins	<p><b><i>“It is possible that the COVID-19 pandemic could delay the timing of the FDA’s approval decisions for liso-cel and ide-cel, which could have a material adverse effect on the CVRs that we issued in connection with the Celgene transaction.”</i></b></p> <p><i>We have submitted BLAs for liso-cel and ide-cel, the two remaining assets underlying the CVRs that we issued in connection with the Celgene transaction (the third CVR asset, Zeposia (ozanimod), was approved earlier this year). These applications are under review by the FDA. Liso-cel has a PDUFA date of November 16, 2020 and ide-cel has a PDUFA date of March 27, 2021. It is possible that COVID-19 could impact FDA operations, including the ability for the FDA to conduct on-site inspections, such that the review of either or both of these CVR assets could be delayed. Any delay in the timing of approval could reduce the resale price of the CVRs. If there is a significant delay that extends the FDA’s review period beyond December 31, 2020 for liso-cel or March 31, 2021 for ide-cel, then no payment will be made under the CVRs and the CVRs will expire without value.”</i></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• No scienter</li> </ul>
22	¶ 201	11/5/20	Source: Earnings Call  Alleged Speakers: Giovanni Caforio Samit Hirawat	<p><b>“Hirawat: From liso-cel perspective, not much to share, except for the fact that we’ve already communicated, we continue our dialogue with the regulatory agencies. . . .</b></p> <p><b>Caforio: The only thing I would add is, just to close on what Samit mentioned with respect to liso-cel, as always, obviously, we will update you as our discussion with the regulatory authorities progress.”</b></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statement subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery</li> <li>• No scienter</li> </ul>

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23	¶ 202	11/5/20	Source: Earnings Call  Alleged Speaker: Samit Hirawat	<p><b>“As we’ve said in the past that the conversations with the agencies are going well, and we look forward to seeing the -- hopefully, the approval at some point to be able to bring to the patients as soon as possible.</b> We’ll obviously let you know as soon as we get the decision. We are not going to comment obviously specifically about the dialogue around inspections, et cetera. We’re generally very happy with the dialogue that has been happening.”</p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Contains forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Contains non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>
24	¶ 205	11/16/20	Source: Press Release  Alleged Speaker: Samit Hirawat	<p><b>“Bristol Myers Squibb continues to work closely with the FDA to support the ongoing review of the BLA for liso-cel</b> said Samit Hirawat, M.D., executive vice president, chief medical officer, global drug development, Bristol Myers Squibb. ‘We are committed to bringing liso-cel to patients with relapsed or refractory large B-cell lymphoma who still have significant unmet need.’</p> <p style="text-align: center;">* * *</p> <p>U.S. FDA approval of liso-cel by December 31, 2020 is one of the required remaining milestones of the Contingent Value Rights issued upon the close of the Celgene acquisition in the fourth quarter of 2019. The other is U.S. FDA approval of Idecabtagene Vicleucel (ide-cel) by March 31, 2021. <b><i>The company is committed to working with the FDA to progress both applications to achieve the remaining regulatory milestones required by the CVR.</i></b></p>	<ul style="list-style-type: none"> <li>• Statements not adequately alleged to be false or misleading</li> <li>• Forward-looking statements subject to PSLRA safe harbor, 15 U.S.C. § 78u-5</li> <li>• Non-actionable puffery or statements of opinion under <i>Omnicare</i></li> <li>• No scienter</li> </ul>